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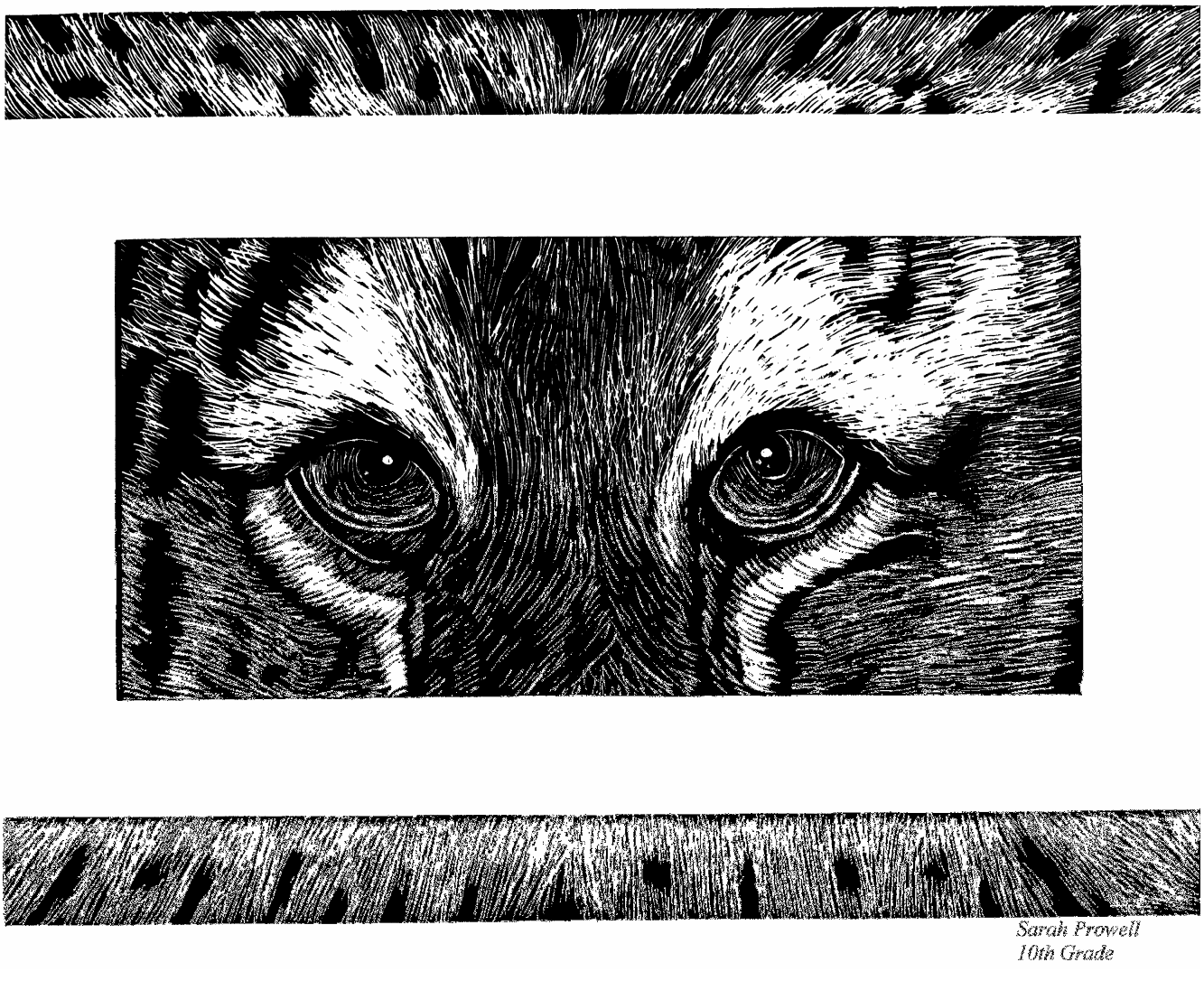

Sarah Prowell
10th Grade

2008 Publication Schedule Inside

School children's artwork is used to decorate the front cover and blank filler pages of the *Texas Register*. Teachers throughout the state submit the drawings for students in grades K-12. The drawings dress up the otherwise gray pages of the *Texas Register* and introduce students to this obscure but important facet of state government.

The artwork featured on the front cover is chosen at random. Inside each issue, the artwork is published on what would otherwise be blank pages in the *Texas Register*. These blank pages are caused by the production process used to print the *Texas Register*.

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Open Meetings

Statewide agencies and regional agencies that extend into four or more counties post meeting notices with the Secretary of State.

Meeting agendas are available on the *Texas Register*'s Internet site:
http://www.sos.state.tx.us/open/index.shtml

Members of the public also may view these notices during regular office hours from a computer terminal in the lobby of the James Earl Rudder Building, 1019 Brazos (corner of 11th Street and Brazos) Austin, Texas. To request a copy by telephone, please call 463-5561 in Austin. For out-of-town callers our toll-free number is 800-226-7199. Or request a copy by email: register@sos.state.tx.us

For items ***not*** available here, contact the agency directly. Items not found here:

- minutes of meetings
- agendas for local government bodies and regional agencies that extend into fewer than four counties
- legislative meetings not subject to the open meetings law

The Office of the Attorney General offers information about the open meetings law, including Frequently Asked Questions, the *Open Meetings Act Handbook*, and Open Meetings Opinions.
http://www.oag.state.tx.us/opinopen/opengovt.shtml

The Attorney General's Open Government Hotline is 512-478-OPEN (478-6736) or toll-free at (877) OPEN TEX (673-6839).

Additional information about state government may be found here:
http://www.state.tx.us/

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Meeting Accessibility. Under the Americans with Disabilities Act, an individual with a disability must have equal opportunity for effective communication and participation in public meetings. Upon request, agencies must provide auxiliary aids and services, such as interpreters for the deaf and hearing impaired, readers, large print or Braille documents. In determining type of auxiliary aid or service, agencies must give primary consideration to the individual's request. Those requesting auxiliary aids or services should notify the contact person listed on the meeting notice several days before the meeting by mail, telephone, or RELAY Texas. TTY: 7-1-1.

PROPOSED RULES

Proposed rules include new rules, amendments to existing rules, and repeals of existing rules. A state agency shall give at least 30 days' notice of its intention to adopt a rule before it adopts the rule. A state agency shall give all interested persons a reasonable opportunity to submit data, views, or arguments, orally or in writing (Government Code, Chapter 2001).

Symbols in proposed rule text. Proposed new language is indicated by underlined text. [~~Square brackets and strikethrough~~] indicate existing rule text that is proposed for deletion. "(No change)" indicates that existing rule text at this level will not be amended.

TITLE 1. ADMINISTRATION

PART 1. OFFICE OF THE GOVERNOR

CHAPTER 3. CRIMINAL JUSTICE DIVISION

The Office of the Governor, Criminal Justice Division (CJD), proposes amendments to Subchapter A §§3.1, 3.3, 3.5, 3.7, 3.9, 3.11, 3.17, and 3.19; Subchapter B §§3.55, 3.71, 3.73, 3.81, 3.83, and 3.85; Subchapter D §3.2023; Subchapter E §§3.2501, 3.2507, 3.2513, 3.2519, and 3.2525; Subchapter G §3.8210 and §3.8220.

The Office of the Governor, Criminal Justice Division (CJD), proposes new rule §3.2025 under Subchapter D. The addition of §3.2025 requires all grant applicants provide CJD with the contact information for their agency's civil rights liaison.

The Office of the Governor, Criminal Justice Division (CJD), proposes the repeal of §3.2511 under Subchapter E. The repeal of §3.2511 removes information regarding the process of requesting grant funds and moves this information into §3.2507.

The amendment to §3.1 remove references to Subchapter C, which is proposed to be repealed.

The amendment to §3.3(9) corrects a formatting error.

The amendment to §3.3(13)(B) adds "DVD players" to the list of items considered to be equipment budget items.

The amendment to §3.5(a)(6) changes the word "obtain" to "access" to clarify the manner in which grant applicants can apply.

The amendment to §3.7: (1) clarifies the language relating to funding decisions; and (2) expands on factors CJD takes into consideration during the grant funding selection process; and (3) removes unnecessary language regarding funding allocations; and (4) gives CJD the flexibility to notify applicants of funding decisions via the internet or other means; and (5) removes an erroneous statement that has been moved to §3.9.

The amendment to §3.9 includes a statement moved from the previous section regarding the finality of funding decisions.

The amendment to §3.11 updates this section to reflect the new process of accepting grant awards through CJD's online grant management system.

The amendment to §3.17: (1) renames this section from "Federal Funding" to "Grant Funding" in order to also be applicable to state funding; and (2) clarifies that grantees must comply with both federal and state statutes, rules, regulations and guidelines that may apply to their funding.

The amendment to §3.19: (1) corrects a typographical error; and (2) corrects the citation from the Code of Federal Regulations; and (3) corrects a second typographical error.

The amendment to §3.55: (1) removes the statement of prohibition on serving adult offenders; and (2) adds a comprehensive list of prohibited costs and activities applying to all grants.

The amendment to §3.71 clarifies language relating to the determination of eligible grant budget items.

The amendment to §3.73 adds a statement requiring that grant applicants who include matching funds in the grant budget maintain that level of matching funds throughout the grant period.

The amendment to §3.81 gives CJD the flexibility to notify applicants via the internet of approved equipment items.

The amendment to §3.83 removes the list of ineligible supplies and direct operating expenses because a complete list of ineligible costs and activities has been added to a previous section.

The amendment to §3.85 clarifies the language of this section to make it easier to understand.

The amendment to §3.2023 adds language requiring all grantees to submit information regarding their agency's fiscal capability in the grant application.

The amendment to §3.2501: (1) removes the requirement for grant officials to provide CJD with a sample signature as a result of CJD's online grant management system; and (2) removes the language requiring grantees to inform CJD of changes to the grant officials in writing; and (3) removes the requirement for new grant officials to provide CJD with a sample signature.

The amendment to §3.2507 adds language to clarify the expenditure reporting process.

The amendment to §3.2513 clarifies changes to the grant adjustment process as a result of CJD's online grant management system.

The amendment to §3.2519 removes the words "in writing" from this section.

The amendment to §3.2525 adds language requiring that grantees' monitoring program incorporates best practices.

The amendment to §3.8210 adds language allowing the Governor to appoint the chairman of the Governor's Juvenile Justice Advisory Board.

The amendment to §3.8220 allows the Governor to appoint individuals to advise the Governor's Juvenile Justice Advisory Board concerning specific juvenile justice matters.

Ken Nicolas, CJD's Executive Director, has determined for the first five-year period that the amendments, new rule, and repeal are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rules. Mr. Nicolas has determined there will not be an effect on small

businesses. There is no anticipated economic cost to persons who are required to comply with the proposed rules.

Mr. Nicolas has also determined that for the first five-year period that the amendments, new rule, and repeal are in effect, the public benefit anticipated as a result of enforcing the sections will be more efficient processes and procedures and the current rules will be more easily understood. There will be no anticipated economic cost to persons or businesses for complying with the proposed rules.

Comments on the proposal may be submitted in writing to Scott Bingaman, Director of Operations, Office of the Governor, Criminal Justice Division, 1100 San Jacinto Blvd., Austin, Texas 78701, (512) 463-1919. Comments may also be submitted electronically to *scott.bingaman@governor.state.tx.us* or faxed to (512) 475-2440. All comments must be received by the director of operations not more than 30 calendar days after notice of a proposed change in the section has been published in the *Texas Register*.

SUBCHAPTER A. GENERAL GRANT PROGRAM PROVISIONS

1 TAC §§3.1, 3.3, 3.5, 3.7, 3.9, 3.11, 3.17, 3.19

The amended rules are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the amendment of these rules.

§3.1. Applicability.

Subchapters A through F of this chapter apply to all applications for funding and grants submitted to the Criminal Justice Division (CJD), Office of the Governor. A grantee must comply with the provisions of Subchapters A through F in effect on the date the grant is awarded by CJD, unless a subsequent effective date is specified by CJD in an original grant award or a grant adjustment. Subchapter A covers the general provisions for grant funding. Subchapter B addresses general eligibility and budget rules for grant funding. [~~Subchapter C outlines specific eligibility and budget rules applicable to various funding sources available to CJD; these rules are in addition to all other general rules in this chapter.~~] Subchapter D provides rules detailing the conditions CJD may place on grants. Subchapter E sets out the rules related to administering grants. Subchapter F specifies rules regarding program monitoring and audits. Subchapter G details the rules regarding CJD advisory boards. Subchapter H addresses Crime Stoppers program certification. Subchapter I adopts the Memorandum of Understanding between CJD and the Texas Department of Public Safety.

§3.3. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless otherwise indicated:

(1) - (8) (No change.)

(9) UGMS: the Uniform Grant Management Standards promulgated by the Governor's Office of Budget and Planning at 1 Texas Administrative Code (TAC) [~~T.A.C.~~] §§5.141 - 5.167;

(10) - (12) (No change.)

(13) equipment:

(A) an article of non-expendable, tangible personal property having a useful life of more than one year and an acquisition cost which equals the lesser of the capitalization level established by the grantee for financial statement purposes or $1,000; or

(B) any of the following items with costs between $500 and $1,000: stereo systems, still and video cameras, facsimile machines, DVD players, VCRs and VCR/TV combinations, cellular and portable telephones, and computer systems.

(14) (No change.)

§3.5. Grant Submission Process.

(a) When applying for a grant pursuant to a Request for Applications (RFA) published in the *Texas Register* by CJD, applicants must submit their applications according to the requirements provided in the RFA. The RFA will provide the following:

(1) - (5) (No change.)

(6) how applicants may access [~~obtain~~] application kits;

(7) - (11) (No change.)

(b) - (c) (No change.)

§3.7. Selection Process.

(a) (No change.)

(b) For applications submitted to CJD pursuant to §3.5(b) of this chapter, the executive director will decide whether to fund the application based upon the following factors:

(1) - (2) (No change.)

(3) whether delaying the application would have a significant negative impact on the area proposed to be served [~~immediate need for the project~~].

(c) For applications prioritized by a COG, the CJAC must prioritize the applications and prepare the priority listing. The COG's governing body must approve the priority listing. The COG then must submit the priority listing to CJD within the time periods established by CJD. CJD will render final funding decisions on these applications based upon the availability of funding, COG priorities, eligibility, and reasonableness[~~, availability of funding, and cost-effectiveness~~]. Preference will be given to applicants who demonstrate cost effective programs focused on a comprehensive and effective approach to services that compliment the Governor's strategies.

[~~(d) For applications prioritized by a COG and seeking funding from the State Criminal Justice Planning Fund, the Juvenile Justice and Delinquency Prevention Act Fund, or the Safe and Drug-Free Schools and Communities Act Fund, CJD will allocate funding through a formula based upon population figures and crime rates. No formula-based funding allocation exists for applications prioritized by a COG that seek grants from other funding sources.~~]

(d) [~~(e)~~] During the review of an application, CJD or its designee may request that the applicant submit additional information necessary to complete the grant review. CJD or its designee may request the applicant to provide any outstanding forms and documents to clarify or justify any part of the application or to disclose other funding sources related to the project. Such requests for information, including the issuance of a preliminary review report, do not serve as notice that CJD intends to fund an application. If CJD is not able to adequately resolve problems within an applicant's budget through the review process, CJD may make the necessary corrections to the budget to bring it into compliance with applicable state or federal requirements. Any corrections to an applicant's budget will be reflected in the award documentation.

(e) [(f)] CJD will inform applicants [in writing] of funding decisions on their grant applications through either a Statement of Grant Award or a notification of denial. For applications prioritized by a COG that do not receive funding recommendations, the COG notification of the decision not to recommend funding serves as the applicant's notification of denial.

[(g) All funding decisions made by the executive director are final and are not subject to appeal.]

§3.9. Grant Funding Decisions.

(a) - (c) (No change.)

(d) All funding decisions made by the executive director are final and are not subject to appeal.

§3.11. Grant Acceptance.

The award documentation constitutes the operative documents obligating and reserving funds for use by the grantee in execution of the program or project covered by the award. Such obligation may be terminated without further cause if the grantee's authorized official fails to properly accept the grant award [sign the Grantee Acceptance Notice, resolve special conditions listed on the Statement of Grant Award, and return them to CJD] within 45 calendar days of the date upon which CJD issues the Statement of Grant Award. CJD may extend this deadline upon written request from the applicant. No funds will be disbursed to the grantee until the grantee has properly accepted the grant [signed Grantee Acceptance Notice has been received by CJD].

§3.17. Grant [Federal] Funding.

All grantees receiving state or federal funds must comply with the applicable statutes, rules, regulations, and guidelines related to the [federal] funding source under which the grant is funded. This chapter provides directly by specific rule or adopts by reference all applicable state and federal statutes, rules, regulations, and guidelines.

§3.19. Adoptions by Reference.

(a) (No change.)

(b) CJD adopts by reference the rules and documents listed below that relate to the administration of CJD grants:

(1) Uniform Grant Management Standards (UGMS) adopted pursuant to the Uniform Grant and Contract Management Act of 1981, Chapter 783, Texas Government Code. See 1 TAC [T.A.C.] §§5.141 - 5.167. These requirements apply to all CJD grants, whether state or federal funds, including grants to nonprofit corporations.

(2) - (9) (No change.)

(10) Texas Review and Comment System (TRACS). See 1TAC [T.A.C.] §5.191 et seq. Developed in response to Presidential Executive Order 12372, as amended by Presidential Executive Order 12416. These requirements apply to all grants funded by CJD, except for those funded under the Crime Stoppers Assistance Fund, State Criminal Justice Planning (421) Fund, Victims of Crime Act Fund, and Drug Court Program. Participation in TRACS, including receiving a favorable review, does not assure grant funding.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702202

Christopher Burnett
Assistant General Counsel
Office of the Governor
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For further information, please call: (512) 463-1919

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SUBCHAPTER B. GENERAL GRANT PROGRAM POLICIES
DIVISION 1. ELIGIBILITY REQUIREMENTS

1 TAC §3.55

The amended rules are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the amendment of these rules.

§3.55. Prohibitions [Legal Services for Adult Offenders].

Grant funds may not be used to support the following services, activities and costs: [CJD will not fund projects that provide legal services for adult offenders.]

(1) Proselytizing or sectarian worship.

(2) Lobbying.

(3) Vehicles or equipment for government agencies that are for general agency use.

(4) Admission fees or tickets to any amusement park, recreational activity or sporting event.

(5) Promotional gifts.

(6) Food, meals, beverages, or other refreshments unless the expense is for a working event where full participation by participants mandates the provision of food and beverages and the event is not related to amusement and/or social activities in any way.

(7) Membership dues for individuals.

(8) Any expense or service that is readily available at no cost to the grant project or that is provided by other federal, state or local funds.

(9) Fundraising.

(10) New construction.

(11) Medical services.

(12) Legal services for adult offenders.

(13) Any other prohibition imposed by federal, state or local law.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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Christopher Burnett
Assistant General Counsel
Office of the Governor
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DIVISION 2. GRANT BUDGET REQUIREMENTS

1 TAC §§3.71, 3.73, 3.81, 3.83, 3.85

The amended rules are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the amendment and addition of these rules.

§3.71. Grant Budgets.

CJD is not obligated to fund budget items in a grant application at the amounts requested by the applicant. CJD will make decisions regarding funding levels for both the overall project and for individual budget items based upon the item's [~~project's~~] reasonableness, eligibility, the availability of grant funding, and cost-effectiveness.

§3.73. Matching Funds Policy.

(a) (No change.)

(b) If matching funds are required on a grant, then the grantee must provide matching funds equal to or greater than the required minimum matching funds percentage of the total grant funds. Grantees will be held to and must report expenses for any matching funds included in the CJD-approved budget.

(c) - (f) (No change.)

§3.81. Equipment.

(a) Applicants must submit with their grant applications an itemized list of all proposed equipment purchases to CJD for approval. Grantees must request any additional equipment purchases through grant adjustments. Grantees are not authorized to purchase any equipment until they have received [~~written~~] approval to do so from CJD through an original grant award or a grant adjustment. Decisions regarding equipment purchases are made based on whether or not the grantee has demonstrated that the requested equipment is necessary, essential to the successful operation of the grant project, and reasonable in cost.

(b) - (c) (No change.)

§3.83. Supplies and Direct Operating Expenses.

[~~(a)~~] Supplies and direct operating expenses are costs directly related to the grantee's day-to-day operation of the grant project that are not included in any of the grantee's other approved budget categories, as defined in §3.3(10) of this chapter, and that have an acquisition cost of less than $1,000 per unit. Grantees must allocate costs on a prorated basis for shared usage.

[~~(b) CJD will not approve grant funds to purchase:~~]

[~~(1) admission fees or tickets to any amusement park, recreational activity, or sporting event; or~~]

[~~(2) promotional gifts.~~]

[~~(c) Unless otherwise allowed by this chapter, grantees cannot use grant funds to pay for food, meals, beverages, or other refreshments unless the expense is for a working event where full participation by participants mandates the provision of food and beverages and that event is not related to amusement and/or social activities in any way.~~]

[~~(d) Grant funds shall not be used to pay membership dues for individuals.~~]

§3.85. Indirect Costs.

(a) CJD may approve indirect costs in the CJD-funded portion of the grant project in an amount not to exceed two percent of the CJD-approved direct costs [~~in the CJD-funded portion of a grant project~~], unless the grantee has an approved cost-allocation plan.

(b) If the applicant has a cost-allocation plan and wishes to charge indirect costs to the CJD-funded or cash match portion of the grant, the applicant shall identify the indirect cost rate and provide supporting documentation as part of the application to CJD. CJD will review the documentation and will determine an appropriate indirect cost rate for the project.

(c) Unless otherwise specified [~~under Subchapter C~~], indirect costs are allowable under CJD grants in accordance with applicable state and federal guidelines.

[~~(d) The Juvenile Accountability Block Grant Program is exempt from this section and instead must comply with §3.1209 of this chapter.~~]

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702204
Christopher Burnett
Assistant General Counsel
Office of the Governor
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For further information, please call: (512) 463-1919

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SUBCHAPTER D. CONDITIONS OF GRANT FUNDING

1 TAC §3.2023, §3.2025

The new and amended rules are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the amendment of these rules.

§3.2023. Tax-Exempt and Nonprofit Information.

All nonprofit corporations applying for grant funds [~~that have not previously received a CJD grant~~] must submit with their application[~~:~~] information about the agency's fiscal capability, including information from the Internal Revenue Service granting the corporation tax-exempt status.

[~~(1) a CJD-prescribed Financial Capability Questionnaire; and~~]

[~~(2) documentation from the Internal Revenue Service granting the corporation tax-exempt status.~~]

§3.2025. Civil Rights Liaison.

All applicants must certify that they have a designated civil rights liaison during the application process. The civil rights liaison will serve as the grantee's civil rights contact point and will bear the responsibility for ensuring that the grantee meets all applicable civil rights requirements. The designee will act as the grantee's liaison in civil rights matters with CJD and with the federal Office of Justice Programs.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

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Christopher Burnett
Assistant General Counsel
Office of the Governor
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For further information, please call: (512) 463-1919

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SUBCHAPTER E. ADMINISTERING GRANTS

1 TAC §3.2501, §3.2507

The amended rules are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the amendment of these rules.

§3.2501. Grant Officials.

(a) - (b) (No change.)

[~~(c) The signature of each grant official must be provided to CJD by the grantee.~~]

(c) [~~(d)~~] The grantee shall make every effort to ensure that each grant official has an e-mail address and access to the Internet.

(d) [~~(e)~~] The grantee shall notify CJD [~~in writing~~] within 20 calendar days of:

(1) any change in the designated project director, financial officer, or authorized official and shall include a sample signature of the new project director, financial officer, or authorized official;

(2) any change in the mailing address, e-mail address, fax number, or telephone number of each grant official; and

(3) any change in the grantee's physical address.

§3.2507. Expenditure Reports and Reimbursement.

(a) Each grantee must submit financial expenditure reports to CJD [~~each calendar quarter~~]. CJD will provide the appropriate forms and instructions for the reports along with deadlines for their submission. Submission of an expenditure report may generate grant payment upon CJD approval. If the grantee fails to submit timely expenditure reports, grantees will not receive grant payments. [~~CJD will place a financial hold on a grantee's funds if the grantee fails to submit timely expenditure reports. Submission of an expenditure report does not generate a grant payment. Section 3.2511 of this chapter sets forth rules for requesting payments.~~] The grantee must report program income in the expenditure report including program income earned by the grantee, a vendor or contractor.

(b) After a grant has been accepted and if there are no outstanding special conditions or other deficiencies, a grantee may submit expenditure reports to generate reimbursement no more than once a month. A grantee may submit an expenditure report to generate payment on a cost reimbursement basis. Grantees may only request an advance payment during the first month of the grant period to cover the first month's expenses. All expenditure reports must be submitted to CJD in accordance with the instructions provided.

(c) Grantees must ensure that CJD receives their final expenditure report no later than the 90th calendar day after the end of the grant period or funds will lapse and revert to the grantor agency. If this date falls on a weekend or a state or federal holiday, then CJD will honor receipt on the next business day. If grant funds are on hold for any reason, these funds will lapse at the end of the above-referenced period and the grantee cannot recover them. CJD will not make payments to grantees that submit their final expenditure report after the above-referenced deadline described by this subsection.

(d) Crime Stoppers Assistance Fund projects are exempt from subsection (a) of this section and instead may request funds through submission of an expenditure report once each quarter on a cost-reimbursement basis only.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

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Christopher Burnett
Assistant General Counsel
Office of the Governor
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 463-1919

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1 TAC §3.2511

(Editor's note: The text of the following section proposed for repeal will not be published. The section may be examined in the Office of the Governor or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repealed rule is proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the repeal of this rule.

§3.2511. Requests for Funds.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

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Christopher Burnett
Assistant General Counsel
Office of the Governor
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 463-1919

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1 TAC §§3.2513, 3.2519, 3.2525

The amended rules are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the amendment of these rules.

§3.2513. Grant Adjustments.

(a) [~~The authorized official must sign requests for grant adjustments that alter the amount of a grant award or the scope of a grant project.~~] The project director, financial officer, or authorized official may submit [~~must sign~~] requests for grant adjustments [~~that do not alter the amount of a grant award or the scope of a grant project~~]. The authorized official must certify all grant adjustment requests.

(b) Budget Adjustments. Adjustments consisting of increases or decreases in the amount of a grant or the reallocation of grant funds among or within approved budget categories, as defined in §3.3(10) of this chapter, are considered budget adjustments, and[~~, except as provided by paragraph (2) of this subsection,~~] are allowable only with prior CJD approval. The following rules apply to budget adjustments:

(1) Changes in the indirect costs category require prior CJD approval through a [~~written~~] grant adjustment notice.

[~~(2) During a grant period, grantees may transfer grant funds among or within the approved budget categories, as defined in §3.3(10) of this chapter, without prior CJD approval as long as the amount transferred does not exceed a cumulative total of ten percent of the CJD-funded portion of a grant project during that grant period; the action does not change the scope of the project; and the change does not conflict with paragraph (1) of this subsection and §3.81(a) of this chapter.~~]

[~~(3) CJD will not approve more than four budget adjustments initiated by a grantee each grant year.~~]

(2) [~~(4)~~] CJD will not approve budget adjustment requests submitted after the end of the grant period [~~within 30 calendar days of the end of the grant period unless the executive director grants an exception~~].

(3) [~~(5)~~] All budget adjustments must comply with all relevant rules in this chapter. The grantee must maintain accurate records that show all budget adjustments.

(c) For supplemental grant awards, the authorized official [~~grantee~~] must accept or reject any additional award within 45 calendar days of the date of the award [~~upon which CJD issues a Grant Adjustment Notice~~] and follow all rules in accordance with §3.11 of this chapter.

(d) Programmatic Changes. The following rules apply to programmatic changes:

(1) Requests to revise the scope, target, or focus of the project, or alter project activities require prior [~~advance written~~] approval from CJD.

(2) A grantee may submit a [~~written~~] request to extend the grant period. The request must be submitted to CJD and received [~~or postmarked~~] no later than the last day of the grant period.

§3.2519. Grant Reduction or Termination.

(a) If a grantee wishes to terminate any approved grant, it must notify CJD [~~in writing~~] immediately.

(b) - (c) (No change.)

§3.2525. Evaluating Project Effectiveness.

(a) (No change.)

(b) Grantees are responsible for managing the day-to-day operations of grant and subgrant supported activities, including those of their contractors and subcontractors. Grantee monitoring must cover each program, function and activity. Grantees must develop, implement, and maintain a standardized monitoring program incorporating best practices to continuously assure grant and subgrant supported activities are monitored. The monitoring program will include, at a minimum, mechanisms by which grantees will ensure they are achieving performance goals and receiving contracted deliverables as specified in agreements and contracts.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702208
Christopher Burnett
Assistant General Counsel
Office of the Governor
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 463-1919

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SUBCHAPTER G. CRIMINAL JUSTICE DIVISION ADVISORY BOARDS
DIVISION 2. GOVERNOR'S JUVENILE JUSTICE ADVISORY BOARD

1 TAC §3.8210, §3.8220

The amended rules are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the amendment of these rules.

§3.8210. Composition.

The composition of the board will be in compliance with the federal Juvenile Justice and Delinquency Prevention Act and all regulations set by the Office of Juvenile Justice and Delinquency Prevention. The governor will appoint the chairman of the board.

§3.8220. Compensation.

(a) (No change.)

(b) The governor, chairman or the executive director of CJD may appoint qualified persons to advise the Juvenile Justice Advisory Board concerning specific juvenile justice matters. Such persons shall serve without compensation but may be reimbursed for reasonable and necessary expenses upon approval of the executive director of CJD.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702209
Christopher Burnett
Assistant General Counsel
Office of the Governor
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 463-1919

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CHAPTER 3. CRIMINAL JUSTICE DIVISION SUBCHAPTER C. FUND-SPECIFIC GRANT POLICIES

The Office of the Governor, Criminal Justice Division (CJD), proposes the repeal of Subchapter C, Division 1 §§3.101, 3.103, 3.105, and 3.111; Division 2 §§3.201,3.203, 3.205, and 3.211; Division 3 §§3.301, 3.303, 3.305, 3.311, and 3.313; Division 4 §§3.401, 3.403, and 3.405; Division 5 §§3.501, 3.503, 3.505, 3.509, 3.511, and 3.513; Division 6 §§3.601, 3.603, 3.605, 3.609, 3.611, and 3.613; Division 7 §§3.701, 3.703, 3.705, 3.711, and 3.717; Division 9 §§3.901, 3.903, and 3.905; Division 11 §§3.1101, 3.1103, 3.1105, 3.1109, and 3.1111; Division 12 §§3.1201, 3.1203, 3.1205, 3.1209, 3.1211, and 3.1213; Division 13 §§3.1301, 3.1303, 3.1305, 3.1309, and 3.1311.

Subchapter C, "Fund-Specific Grant Policies" outlines specific eligibility and budget rules applicable to various funding sources administered by CJD. For federal fund sources, these rules and guidelines are available in the federal guidelines. Information on grant guidelines can be found on CJD's website.

The Office of the Governor, Criminal Justice Division (CJD), proposes the repeal of §3.2511 under Subchapter E. The repeal of §3.2511 removes information regarding the process of requesting grant funds and moves this information into §3.2507.

Ken Nicolas, CJD's Executive Director, has determined for the first five-year period that the repeals are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rules. Mr. Nicolas has determined there will not be an effect on small businesses. There is no anticipated economic cost to persons who are required to comply with the proposed rules.

Mr. Nicolas has also determined that for the first five-year period that the repeals are in effect, the public benefit anticipated as a result of enforcing the sections will be more efficient processes and procedures and the current rules will be more easily understood. There will be no anticipated economic cost to persons or businesses for complying with the proposed rules.

Comments on the proposal may be submitted in writing to Scott Bingaman, Director of Operations, Office of the Governor, Criminal Justice Division, 1100 San Jacinto Blvd., Austin, Texas 78701, (512) 463-1919. Comments may also be submitted electronically to *scott.bingaman@governor.state.tx.us* or faxed to (512) 475-2440. All comments must be received by the director of operations not more than 30 calendar days after notice of a proposed change in the section has been published in the *Texas Register*.

DIVISION 1. STATE CRIMINAL JUSTICE PLANNING (421) FUND

1 TAC §§3.101, 3.103, 3.105, 3.111

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the Office of the Governor or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the repeal of these rules.

§3.101. Source and Purpose.

§3.103. Project Requirements.

§3.105. Eligible Applicants.

§3.111. Ineligible Activities.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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TRD-200702229
Christopher Burnett
Assistant General Counsel
Office of the Governor
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 463-1919

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DIVISION 2. JUVENILE JUSTICE AND DELINQUENCY PREVENTION ACT FUND

1 TAC §§3.201, 3.203, 3.205, 3.211

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the Office of the Governor or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the repeal of these rules.

§3.201. Source and Purpose.

§3.203. Project Requirements.

§3.205. Eligible Applicants.

§3.211. Ineligible Activities and Costs.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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Christopher Burnett
Assistant General Counsel
Office of the Governor
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For further information, please call: (512) 463-1919

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DIVISION 3. TITLE V DELINQUENCY PREVENTION ACT FUND

1 TAC §§3.301, 3.303, 3.305, 3.311, 3.313

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the Office of the Governor or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the repeal of these rules.

§3.301. Source and Purpose.

§3.303. Project Requirements.

§3.305. Eligible Applicants.

§3.311. Years of Funding.

§3.313. Prevention Policy Board.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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Christopher Burnett
Assistant General Counsel
Office of the Governor
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DIVISION 4. SAFE AND DRUG-FREE SCHOOLS AND COMMUNITIES ACT FUND

1 TAC §§3.401, 3.403, 3.405

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the Office of the Governor or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the repeal of these rules.

§3.401. Source and Purpose.

§3.403. Project Requirements.

§3.405. Eligible Applicants.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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Christopher Burnett
Assistant General Counsel
Office of the Governor
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DIVISION 5. VICTIMS OF CRIME ACT FUND

1 TAC §§3.501, 3.503, 3.505, 3.509, 3.511, 3.513

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the Office of the Governor or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the repeal of these rules.

§3.501. Source and Purpose.

§3.503. Project Requirements.

§3.505. Eligible Applicants.

§3.509. Indirect Costs.

§3.511. Ineligible Activities and Costs.

§3.513. Civil Rights Liaison Certification.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702233

Christopher Burnett
Assistant General Counsel
Office of the Governor
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For further information, please call: (512) 463-1919

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DIVISION 6. CRIME STOPPERS ASSISTANCE FUND

1 TAC §§3.601, 3.603, 3.605, 3.609, 3.611, 3.613

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the Office of the Governor or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the repeal of these rules.

§3.601. Source and Purpose.

§3.603. Project Requirements.

§3.605. Eligible Applicants.

§3.609. Indirect Costs.

§3.611. Ineligible Expenses.

§3.613. Effect of Decertification or Expiration of Certification.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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Christopher Burnett
Assistant General Counsel
Office of the Governor
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DIVISION 7. EDWARD BYRNE MEMORIAL JUSTICE ASSISTANCE GRANT PROGRAM

1 TAC §§3.701, 3.703, 3.705, 3.711, 3.717

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the Office of the Governor or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the repeal of these rules.

§3.701. Source and Purpose.

§3.703. Project Requirements.

§3.705. Eligible Applicants.

§3.711. Ineligible Activities and Costs.

§3.717. Confidential Funds.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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Christopher Burnett
Assistant General Counsel
Office of the Governor
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DIVISION 9. S.T.O.P. VIOLENCE AGAINST WOMEN ACT FUND

1 TAC §§3.901, 3.903, 3.905

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the Office of the Governor or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the repeal of these rules.

§3.901. Source and Purpose.

§3.903. Project Requirements.

§3.905. Eligible Applicants.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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Christopher Burnett
Assistant General Counsel
Office of the Governor
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DIVISION 11. RESIDENTIAL SUBSTANCE ABUSE TREATMENT GRANT PROGRAM

1 TAC §§3.1101, 3.1103, 3.1105, 3.1109, 3.1111

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the Office of the Governor or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the repeal of these rules.

§3.1101. Source and Purpose.

§3.1103. Project Requirements.

§3.1105. Eligible Applicants.

§3.1109. Indirect Costs.

§3.1111. Ineligible Activities and Costs.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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Christopher Burnett
Assistant General Counsel
Office of the Governor
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For further information, please call: (512) 463-1919

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DIVISION 12. JUVENILE ACCOUNTABILITY BLOCK GRANT PROGRAM

1 TAC §§3.1201, 3.1203, 3.1205, 3.1209, 3.1211, 3.1213

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the Office of the Governor or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the repeal of these rules.

§3.1201. Source and Purpose.

§3.1203. Project Requirements.

§3.1205. Eligible Applicants.

§3.1209. Indirect Costs.

§3.1211. Waiver of Application.

§3.1213. JABG Local Advisory Board.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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TRD-200702241
Christopher Burnett
Assistant General Counsel
Office of the Governor
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 463-1919

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DIVISION 13. COVERDELL FORENSIC SCIENCES PROGRAM

1 TAC §§3.1301, 3.1303, 3.1305, 3.1309, 3.1311

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the Office of the Governor or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under Texas Government Code, Title 7, §772.006(a), which requires CJD to award and administer state and federal grant programs, and to assist the Governor in developing policies, plans, programs, and proposed legislation for improving the coordination, administration, and effectiveness of the criminal justice system.

No other statutes, articles, or codes are affected by the repeal of these rules.

§3.1301. Source and Purpose.
§3.1303. Project Requirements.
§3.1305. Eligible Applicants.
§3.1309. Indirect Costs.
§3.1311. Ineligible Activities and Costs.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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Christopher Burnett
Assistant General Counsel
Office of the Governor
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 463-1919

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TITLE 19. EDUCATION

PART 1. TEXAS HIGHER EDUCATION COORDINATING BOARD

CHAPTER 21. STUDENT SERVICES

SUBCHAPTER CC. EARLY HIGH SCHOOL GRADUATION SCHOLARSHIP PROGRAM

19 TAC §21.953, §21.956

The Texas Higher Education Coordinating Board proposes amendments to §21.953 and §21.956 concerning the Early High School Graduation Scholarship Program. The proposed changes are based on new legislation passed by the 80th Texas Legislature and, in particular, House Bill 2383, which changed

the eligibility for scholarships for students graduating on or after September 1, 2007, the effective date of the bill. Specifically, the amendment to §21.953(b) indicates the provisions of that paragraph only apply to students graduating between September 1, 2005, and August 31, 2007. The amendments to §21.953(c) indicate that although they must meet other program requirements, students who graduate on or after September 1, 2007: (1) do not have to be Texas residents at the time they use their awards but must be United States citizens or otherwise lawfully authorized to be present in the United States, (2) must complete the majority (not all) of their high school attendance in Texas, and (3) if they graduate in more than 41 months, they may receive scholarships if they graduate in less than 46 (not 45) months. The amendments to §21.956 clarify that the award amount that can be received by a student graduating in more than 41 but less than 46 months will equal $1,000 if the student meets other program eligibility requirements.

Ms. Lois Hollis, Assistant Commissioner for Student Services, in keeping with the Legislative Budget Board's fiscal note for Senate Bill 201, has determined that for each year of the first five years the amendments are in effect, there will be no significant fiscal implications to state or local government as a result of enforcing or administering the rules.

Ms. Hollis has also determined that for each year of the first five years the amendments are in effect the public benefit anticipated as a result of administering the sections will be that more students graduating from high school with a significant number of college credits will be able to receive financial assistance to continue their studies on a college level. There is no effect on small businesses. There are no anticipated economic costs to persons who are required to comply with the section as proposed. There is no impact on local employment.

Comments on the proposal may be submitted to Lois Hollis, P.O. Box 12788, Austin, Texas 78711, (512) 427-6465, Lois.Hollis@thecb.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

The amendments are proposed under the Texas Education Code, §56.209, which provides the Coordinating Board with the authority to adopt any rules necessary to administer Texas Education Code, Chapter 56, Subchapter K, relating to the Early High School Graduation Scholarship Program.

The amendments affect Texas Education Code, §§56.201 - 56.210.

§21.953. Eligible Students.

(a) (No change.)

(b) To receive an award through the Early High School Graduation Scholarship Program, a student who graduated from high school on or after September 1, 2005, but prior to September 1, 2007, must:

(1) - (4) (No change.)

(c) To receive an award through the Early High School Graduation Scholarship Program, a student who graduated from high school on or after September 1, 2007, must:

(1) be a citizen of the United States or otherwise lawfully authorized to be present in the United States;

(2) have attended one or more public high schools in Texas for the majority of time the person attended high school;

(3) have successfully completed the Recommended or Distinguished Achievement Program-Advanced High School Program established under Texas Education Code, §28.025, unless the principal or other authorized representative of the student's high school provides a written explanation along with the student's transcript and exemption program application that the courses in the Recommended or Advanced High School Program which the student did not complete were unavailable to the student at the appropriate time in his or her high school career because of:

(A) shortage of qualified teachers;

(B) lack of enrollment capacity; or

(C) another cause not within the person's control, an explanation for which is provided on the transcript by the official;

(4) have graduated:

(A) in not more than 41 consecutive months; or

(B) in not more than 46 consecutive months, if the student graduated with at least 30 hours of college credit.

(d) [~~(c)~~] A student's eligibility to receive a tuition credit under the Early High School Graduation Scholarship Program begins with the first regular semester or term following the student's graduation, exclusive of summer sessions that immediately follow the student's graduation. A student's eligibility to receive a tuition credit under the program ends six years after it begins, unless the student seeks and is granted an extension under §21.960 of this title (relating to Hardship Extensions).

§21.956. Award Amounts and Processing Cycle.

(a) (No change.)

(b) For students whose graduation date is on or after September 1, 2005:

(1) the aggregate amount of state credit that may be awarded to a student through this program is:

(A) - (B) (No change.)

(C) $1,000 to apply toward tuition and mandatory fees if the student completed the Recommended or Distinguished Achievement Program-Advanced High School Program and, either:

(i) graduated prior to September 1, 2007, from high school in more than 41 consecutive months but not more than 45 consecutive months with at least 30 hours of college credit; or[.]

(ii) graduated on or after September 1, 2007, from high school in more than 41 consecutive months but not more than 46 consecutive months with at least 30 hours of college credit.

(2) - (3) (No change.)

(c) (No change.)

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702211
Bill Franz
General Counsel
Texas Higher Education Coordinating Board
Proposed date of adoption: July 19, 2007
For further information, please call: (512) 427-6114

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PART 2. TEXAS EDUCATION AGENCY

CHAPTER 97. PLANNING AND ACCOUNTABILITY

SUBCHAPTER DD. INVESTIGATIVE REPORTS, SANCTIONS, AND RECORD REVIEWS

19 TAC §§97.1031, 97.1033, 97.1035, 97.1037

The Texas Education Agency (TEA) proposes amendments to §§97.1031, 97.1033, and 97.1035, concerning investigative reports and sanctions, and new §97.1037, concerning record review of certain decisions. The existing sections define the procedures for on-site investigations and reports as required by Texas Education Code (TEC), §39.076, and procedures for accreditation sanctions under TEC, §39.131, resulting from such reports. The proposed amendments would update and clarify these procedures. The proposed new rule would establish procedures for creating an administrative record for review by the State Office of Administrative Hearings (SOAH). The proposed rule actions would reflect changes in the TEC, Chapter 39, required by House Bill (HB) 1, 79th Texas Legislature, Third Called Session, 2006.

TEC, §39.302, added by HB 1, requires that an opportunity for challenging the decision of the commissioner of education on certain accreditation sanctions be available in specified circumstances and provided by the SOAH. In addition to enacting new TEC, §39.302, HB 1 enacted numerous changes to the TEC, Chapter 39, requiring that existing rules be revised and updated.

Currently, the rules in 19 TAC Chapter 97, Planning and Accountability, Subchapter DD, Procedures for Investigative Reports and Sanctions, define the procedures for on-site investigations and reports as required by TEC, §39.076, and procedures for accreditation sanctions under TEC, §39.131, resulting from such reports. The rules provide for notice to any person whom the report finds to have committed a violation of law, rule, or policy, and provide for an informal review of such findings before they may become final.

The proposed revisions to 19 TAC Chapter 97, Subchapter DD, would update and clarify existing rules in light of HB 1. In addition, the proposal would add a new rule establishing procedures for creating an administrative record for review by the SOAH under new TEC, §39.302. Specifically, the proposed revisions would establish the following.

Section 97.1031, Preliminary Investigative Report, would be amended by adding language in subsection (a) to clarify that an academic accountability rating, a financial accountability rating, and a determination of adequate yearly progress are not considered findings resulting from an investigation under the TEC, Chapter 39, Subchapter D, and do not need to be presented in a preliminary investigative report. The proposal would also address a rating or determination that may be lowered or changed as a result of such an investigation.

Section 97.1033, Informal Review of Preliminary Investigative Report; Final Investigative Report, would be amended in subsection (c) to clarify discussion of findings and/or acceptance of additional written information. Additional minor technical corrections would be made throughout the section.

Section 97.1035, Procedures for Accreditation Sanctions, would be revised to reference proposed new 19 TAC Chapter 97, Subchapter EE, Accreditation Status, Standards, and Sanctions. Existing subsections (a) - (c), which reference outdated TEC provisions, would be deleted. Re-lettered subsections (a) - (d) would address notification to the district, compliance with proposed revisions in §97.1031 and §97.1033, and annual and quarterly review of sanctions and assignments of conservators or management teams.

Proposed new §97.1037, Record Review of Certain Decisions, would be added to establish procedures for creating an administrative record for review by the SOAH for certain decisions. This proposed new rule would apply only to: a notice relating to accreditation sanctions, an assignment of an accreditation status of Accredited-Warned or Accredited-Probation, an assignment of a board of managers, and a request for review of an audit recovery from an open-enrollment charter school. The proposed new rule would address the required notice, request for record review, preliminary matters, record review, final order, no request for record review, and other law.

In addition, the subchapter name would be changed from "Procedures for Investigative Reports and Sanctions" to "Investigative Reports, Sanctions, and Record Reviews" to reflect the new provisions relating to record reviews of certain decisions.

David Anderson, general counsel, has determined that for the first five-year period the amendments and new section are in effect there will be no fiscal implications for state and local government as a result of enforcing or administering the amendments or new section. The proposed rule actions would add clarification of law to the required assignment of investigative reports and sanctions under HB 1, 79th Texas Legislature, Third Called Session, 2006. The proposed rule actions would assign no additional fiscal burden beyond what already is imposed by law. The TEA division responsible for program monitoring and interventions received personnel resources to implement the sanction requirements in HB 1.

Mr. Anderson has determined that for each year of the first five years the amendments are in effect the public benefit anticipated as a result of enforcing the amendments would be to update and clarify procedures for on-site investigations and reports and for accreditation sanctions resulting from such reports in light of HB 1. The public benefit anticipated as a result of enforcing the new section would be to ensure that entities are afforded appropriate administrative review of certain accreditation sanctions and to provide guidelines for the agency for the conduct of such reviews. There will be no effect on small businesses. There is no anticipated economic cost to persons who are required to comply with the amendments and new section.

The public comment period on the proposal begins June 15, 2007, and ends July 15, 2007. Comments on the proposal may be submitted to Cristina De La Fuente-Valadez, Policy Coordination Division, Texas Education Agency, 1701 North Congress Avenue, Austin, Texas 78701, (512) 475-1497. Comments may also be submitted electronically to *rules@tea.state.tx.us* or faxed to (512) 463-0028. All requests for a public hearing on the proposed amendments and new section submitted under the Administrative Procedure Act must be received by the commissioner of education not more than 15 calendar days after notice of the proposal has been published in the *Texas Register*.

The amendments and new section are proposed under the Texas Education Code (TEC), §39.076, which authorizes the agency to adopt written procedures for conducting on-site investigations under TEC, Chapter 39, Subchapter D; and TEC, §39.302, which

authorizes the agency to establish procedures for creating an administrative record for review by the State Office of Administrative Hearings for certain decisions.

The amendments and new section implement the Texas Education Code, §39.076 and §39.302.

§97.1031. Preliminary Investigative Report.

(a) Findings resulting from an investigation under Texas Education Code (TEC), Chapter 39, Subchapter D, [~~§39.074 and §39.075,~~] must be presented in a preliminary investigative report.

(1) The following are not findings resulting from an investigation under TEC, Chapter 39, Subchapter D, and need not be presented in a preliminary investigative report:

(A) an academic accountability rating assigned under §97.1001 of this title (relating to Accountability Rating System);

(B) a financial accountability rating assigned under §109.1002 of this title (relating to Financial Accountability Ratings); or

(C) a determination of adequate yearly progress under §97.1004 of this title (relating to Adequate Yearly Progress).

(2) A rating or determination initially issued under paragraph (1) of this subsection may be lowered or changed as a result of an investigation under TEC, Chapter 39, Subchapter D. In this event, the new rating or determination is a finding resulting from an investigation and must be presented in a preliminary investigative report.

(b) Before issuing a final investigative report, the Texas Education Agency (TEA) must notify the person whom the TEA proposes to find has violated a law, rule, or policy. The notice must be in writing and must:

(1) include a copy of a preliminary investigative report finding that the person has violated a law, rule, or policy;

(2) state the procedures for obtaining an informal review of the findings in the preliminary investigative report under TEC, §39.076(b), including the name and department of the person to whom the request may be addressed; and

(3) set a deadline, which shall not be less than ten calendar days from the date of mailing of the preliminary investigative report, for requesting an informal review of such findings.

§97.1033. Informal Review of Preliminary Investigative Report; Final Investigative Report.

(a) A person who is found in a preliminary investigative report to have violated a law, rule, or policy may request, in writing, an informal review under this section.

(b) A written request for informal review of the preliminary investigative report must be addressed to the Texas Education Agency (TEA) representative identified in the notice under §97.1031(b)(2) of this title (relating to Preliminary Investigative Report). The written request must be received by the TEA representative on or before the deadline specified in §97.1031(b)(3) of this title.

(c) The person requesting the informal review of the preliminary investigative report may submit written information to the TEA representative identified in the notice under §97.1031(b)(2) of this title. In addition, the TEA representative may meet with the person at TEA headquarters in Austin, Texas, to discuss the findings and/or [~~and~~] accept additional written information for review.

(d) Following the informal review of the preliminary investigative report by the TEA representative identified in the notice under §97.1031(b)(2) of this title, a final investigative report will be issued. The final report may include changes or additions to the preliminary investigative report and such modifications are not subject to another informal review procedure.

(e) If no informal review of the preliminary investigative report is requested by the deadline specified in §97.1031 of this title, or if no violation of law, rule, or policy is found in the report, a final investigative report may be issued without informal review.

(f) An informal review of the preliminary investigative report is not governed by Texas Education Code, §7.057, or by Government Code, Chapter 2001.

§97.1035. Procedures for Accreditation Sanctions.

[~~(a) If the commissioner of education finds that a district, campus, or open-enrollment charter school does not satisfy applicable accreditation criteria, the commissioner may lower its accreditation rating and take appropriate action under Texas Education Code (TEC), §39.131.~~]

[~~(b) Regardless of whether the commissioner lowers the accreditation rating under subsection (a) of this section, the commissioner may take action under TEC, §39.131(a)(1) - (8), if the commissioner determines that the action is necessary to improve any area of performance by the district or open-enrollment charter school.~~]

[~~(c) Subject to subsection (f) of this section, once the commissioner takes action under TEC, §39.131, the commissioner may take any other action under that section to the extent the commissioner determines necessary.~~]

(a) [~~(d)~~] The commissioner of education shall notify the school district or open-enrollment charter school in writing of a sanction imposed under Subchapter EE of this chapter (relating to Accreditation Status, Standards, and Sanctions) and this section. The notice must state the basis for finding [~~finding(s) indicating~~] that the district or open-enrollment charter school does not satisfy the applicable accreditation criteria as indicated in Subchapter EE of this chapter. The finding(s) may [~~must~~] be made in the notice or in a final investigative report, or based on a final investigative report.

(b) If a finding is made for the first time in the notice required by subsection (a) of this section, the Texas Education Agency shall comply with §97.1031(b) of this title (relating to Preliminary Investigative Report) and §97.1033 of this title (relating to Informal Review of Preliminary Investigative Report; Final Investigative Report) with respect to the new finding.

(c) [~~(e)~~] A determination under §97.1057 of this title (relating to Accreditation Sanctions) [~~subsections (b) and (c) of this section~~] must be made in writing and may [~~must~~] be included in a written notice under subsection (a) [~~(d)~~] of this section. The determination may [~~must~~] be made in the notice or in a final investigative report, or based on a final investigative report. A determination under §97.1057 of this title [~~subsection (c) of this section~~] may be based on a report on the progress of a prior action under Subchapter EE of this chapter [~~TEC, §39.131~~].

(d) [~~(f)~~] The commissioner shall annually review a sanction imposed under subsection (a) of this section and shall increase the sanction, as required by TEC, §39.133 [~~§39.131(c)~~]. The commissioner shall quarterly review the need for a conservator [~~master~~] or a management team imposed under Subchapter EE of this chapter [~~subsections (a) or (b) of this section~~], as required by TEC, §39.135 [~~§39.131(e)~~]. If reviews are required under both TEC, §39.133 and §39.135 [~~§39.131(c) and (e)~~], a quarterly review under TEC, §39.135, [~~§39.131(e)~~] may satisfy the annual review under TEC, §39.133 [~~§39.131(c)~~]. An annual or quarterly review is not subject to the requirements of [~~subsections (a) through (e) of~~] this section or §97.1057 of this title.

§97.1037. Record Review of Certain Decisions.

(a) Applicability. This section applies only to:

(1) a notice under §97.1035 of this title (relating to Procedures for Accreditation Sanctions) proposing to order:

(A) alternative management of a school district campus or a charter school campus under TEC, §39.1327;

(B) closure of a school district or an open-enrollment charter school under TEC, §§39.071(c), 39.131(a), or 39.1321(c); or

(C) closure of a school district campus or charter school campus under TEC, §39.1324 or §39.1327;

(2) assignment under §97.1055 of this title (relating to Accreditation Status) of an accreditation status of Accredited-Warned or Accredited-Probation;

(3) assignment of a board of managers under TEC, §39.136 and §39.131(a)(9), or TEC, §39.1324(c); or

(4) request for review of an audit recovery from an open-enrollment charter school granted by the commissioner of education under §100.1041(e)(5) of this title (relating to State Funding).

(b) Notice. Notice of a proposed order subject to this section shall be made as provided by §97.1035(d) of this title and this section.

(1) The notice shall attach or make reference to any Texas Education Agency (TEA) reports, final investigative reports, or other information on which the proposed order is based.

(A) Information maintained on the TEA website may be referenced by providing a general citation to the information.

(B) TEA reports previously sent to the district, charter, or campus may be referenced by providing the title and date of the report.

(C) On request, the TEA shall provide copies of, or reasonable access to, information referenced in the notice.

(2) The notice shall state the procedures for requesting a record review of the proposed order under this section, including the name and department of the TEA representative to whom a request for record review may be addressed.

(3) The notice shall set a deadline for requesting a record review, which shall not be less than ten calendar days from the date of mailing of the notice.

(c) Request. The superintendent of the district or chief operating officer of the open-enrollment charter school may request, in writing, a record review under this section.

(1) The request must be properly addressed to the TEA representative identified in the notice under subsection (b)(2) of this section, and must be received by the TEA representative on or before the deadline specified in subsection (b)(3) of this section.

(2) A timely and sufficient request for record review is a prerequisite for an appeal of the proposed order under Chapter 157, Subchapter EE, of this title (relating to Review By State Office of Administrative Hearings: Certain Accreditation Sanctions).

(d) Preliminary matters.

(1) In response to a request under subsection (c) of this section, the TEA representative shall provide written notice to the district or charter of the date, time, and place for the record review.

(A) In this written notice, the TEA representative may:

(i) set time limits for presentations on the record;

(ii) set deadlines for exchanging documents prior to the record review;

(iii) set deadlines for identifying participants who may present information or ask questions during the review; and

(iv) provide any other instructions on the conduct of the record review.

(B) The TEA representative may consider reasonable requests to reschedule the record review and associated deadlines, but shall give primary importance to the need for a speedy resolution of the matter under review.

(C) The record review should in all instances be completed on or before the expiration of 30 calendar days following receipt of the request under subsection (c) of this section.

(D) Timely completion of the record review under subsection (c) of this section is a prerequisite for an appeal of the proposed order under Chapter 157, Subchapter EE, of this title.

(2) The district or charter shall submit any written information to the TEA representative in advance of the record review. To be considered part of the record, such information must also be presented during the review.

(3) In its request for record review, or within a reasonable time thereafter, the district or charter may request that specific TEA staff members attend the record review to assist the TEA representative in reviewing the information presented.

(A) Such request shall be limited to staff directly involved in the development of the information identified in the notice under subsection (b) of this section.

(B) If reasonable and practicable, the TEA representative shall schedule the record review so as to allow the requested staff to attend.

(4) At all times prior to the record review, the district or charter is encouraged to contact the office of the TEA representative to discuss the process and to facilitate preliminary matters. However, such communications will not be recorded and will not be considered part of the record.

(5) The county-district or campus identification number of the affected entity must be included in all written correspondence on the record review, as well as the date the notice was issued under subsection (b) of this section. Correspondence relating to the review may be made part of the record.

(6) All deadlines under this section shall be calculated from the date of actual receipt. No mailbox rule applies.

(e) Record review.

(1) The TEA representative shall meet with the superintendent and/or representatives of the district or charter at the TEA headquarters in Austin, Texas, to receive oral and written information on the proposed order.

(2) The proceedings shall be recorded by audiotape or similar means. The audiotape and all written information presented during the review shall comprise the official record of the proceedings.

(3) The district or charter may have legal counsel present during the proceedings.

(4) The district or charter may present information verbally and in writing, and may rebut information presented by the TEA staff.

(5) The rules of evidence do not apply. Presentations need not follow question-and-answer format.

(6) The district or charter may ask questions of the TEA staff. The TEA representative may designate a specific portion of the meeting for this purpose.

(7) The TEA representative may ask questions of any participant directly or through the TEA staff.

(8) The TEA representative shall strictly confine presentations and questions to the matters set forth in the notice, and shall exclude information that is irrelevant, immaterial, or unduly repetitious.

(9) On request, the TEA representative shall include in the record a brief written proffer describing any information excluded under paragraph (8) of this subsection. In lieu of a written proffer, an oral statement may be recorded on a separate audiotape. If the excluded information is in writing, the document shall be identified as excluded and preserved with the record.

(10) The TEA representative may take official notice of generally recognized information within the TEA's area of specialized knowledge.

(A) Each party shall be notified either before or during the record review, or by reference in a preliminary report or otherwise, of the material officially noticed, including staff memoranda or information.

(B) Any participant may present information to rebut information that is officially noticed.

(11) The special skills and knowledge of the TEA representative and staff shall be used in evaluating all information presented during the record review.

(12) At the request of the district or charter, a record review may be conducted by telephone or similar means.

(13) A participant may present information via telephone or similar means during any record review.

(f) Final order. Following the record review, a final order will be issued. The final order may include changes or additions to the proposed order and such modifications are not subject to another record review procedure. This order may be appealed only as provided by Chapter 157, Subchapter EE, of this title.

(g) No request. If no record review is requested by the deadline specified in subsection (b)(3) of this section, a final order may be issued without record review. An order issued without record review may not be appealed under Chapter 157, Subchapter EE, of this title, or otherwise.

(1) The charter of an open-enrollment charter school is automatically:

(A) revoked, void, and of no further force or effect on the effective date of a final decision by the commissioner of education ordering the school district or charter school closed under this subsection; and

(B) modified to remove authorization for an individual campus on the effective date of a final decision by the commissioner ordering the campus closed under this subsection.

(2) If sanctions are imposed on an open-enrollment charter school under the procedures provided by this subsection, a charter school is not entitled to an additional hearing relating to the modification, placement on probation, revocation, or denial of renewal of a charter as provided by TEC, Chapter 12, Subchapter D.

(h) Other law. Government Code, Chapter 2001, and TEC, §7.057, do not apply to a record review under this section.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702222
Cristina De La Fuente-Valadez
Director, Policy Coordination
Texas Education Agency
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 475-1497

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SUBCHAPTER EE. ACCREDITATION STATUS, STANDARDS, AND SANCTIONS

19 TAC §§97.1051, 97.1053, 97.1055, 97.1057, 97.1059, 97.1061, 97.1063, 97.1065, 97.1067, 97.1069, 97.1071, 97.1073

The Texas Education Agency (TEA) proposes new §§97.1051, 97.1053. 97.1055, 97.1057, 97.1059, 97.1061, 97.1063, 97.1065, 97.1067, 97.1069, 97.1071, and 97.1073, concerning accreditation statuses, standards, and sanctions. The proposed new sections would define the accreditation statuses of Accredited, Accredited-Warned, Accredited-Probation, and Not Accredited-Revoked and would state how accreditation statuses would be determined and assigned to school districts. The proposal would also establish accreditation standards and sanctions, including definitions, purpose, technical assistance teams, campus intervention teams, reconstitution, campus closure, alternative management, intervention stages, and oversight appointments. The proposal reflects changes required by House Bill (HB) 1, 79th Texas Legislature, Third Called Session, 2006.

HB 1 amended the Texas Education Code (TEC), Chapter 39, Public School System Accountability, and, as a result of these changes, new rules must be proposed to implement the changes. The proposed new 19 TAC Chapter 97, Planning and Accountability, Subchapter EE, Accreditation Status, Standards, and Sanctions, would establish new rules to ensure compliance with HB 1, as follows.

Proposed new 19 TAC §97.1051, Definitions, would define by rule, for the purposes of the subchapter, a number of terms, including "campus," "campus closure," and "reconstitution."

Proposed new 19 TAC §97.1053, Purpose, would specify that the requirements of the TEC, Chapter 39, and the proposed new subchapter would apply to an open-enrollment charter school in the same manner as to a district. The proposed new rule would state in rule the statutory purposes of accreditation statuses and sanctions. The proposal would also explain that the accreditation status assigned to a district under this new subchapter would reflect performance beginning with the district's 2007 ratings; however, performance for earlier years would be considered for the purposes of accreditation sanctions.

Proposed new 19 TAC §97.1055, Accreditation Status, would define the requirements a school district must meet each school year to receive the status of Accredited and would state how the

accreditation statuses of Accredited-Warned, Accredited-Probation, and Not Accredited-Revoked would be determined, in accordance with the TEC, §39.071. The proposed rule would also provide the process the commissioner and district must follow when the commissioner determines a district's accreditation status to be Accredited-Warned or Accredited-Probation, including required notification of such status to parents of students enrolled in the district and property owners in the district.

Proposed new 19 TAC §97.1057, Accreditation Sanctions, would establish that if a district or campus does not satisfy the accreditation criteria, the commissioner may lower its accreditation status, academic accountability rating, or financial accountability rating or take any other action under the subchapter to the extent the commissioner determines is reasonably required.

Proposed new 19 TAC §97.1059, Standards for All Accreditation Sanction Determinations, would reflect certain standards to be used by the commissioner in determining sanctions. The rule would state that the commissioner shall impose sanctions individually or in combination as determined necessary to achieve the purposes of the sanctions and shall consider the seriousness, number, extent, and duration of deficiencies identified by the TEA in determining sanctions.

Proposed new 19 TAC §97.1061, Technical Assistance Team Campuses, would reference the annual assignment of a technical assistance team to a campus rated Academically Acceptable if that campus would be rated Academically Unacceptable using the accountability standards for the subsequent year. The proposed new rule would address the waiver of this requirement under standards adopted in the applicable annual accountability manual. The section also would define the composition and discuss the activities of the technical assistance team.

Proposed new 19 TAC §97.1063, Campus Intervention Team; Reconstitution, would implement the provisions of HB 1 related to campuses rated Academically Unacceptable under the state academic accountability rating system and the assignment of a campus intervention team (CIT) to those campuses. Additionally, the section would outline the obligation of certain principals to participate in the School Leadership Pilot Program and the district's responsibility for covering costs associated with the program. The section also would define the timeline under which a campus can and/or would be ordered to undergo reconstitution. In addition, the proposed new rule would describe the activities in which the district, campus, and the CIT must engage to facilitate the reconstitution, including timelines and activities related to the retention or removal of campus educators, including the principal. The proposed new rule also discusses circumstances under which the TEA may assign a monitor, conservator, management team, or board of managers to the campus to ensure the implementation of its school improvement/reconstitution plan and when the TEA may order alternative management or closure of the campus.

Proposed new 19 TAC §97.1065, Campus Closure or Alternative Management, would implement the provisions of HB 1 related to circumstances under which the commissioner orders and/or is required to order alternative management or closure of a campus. The proposed new rule would clarify that the commissioner may take other actions in combination with actions taken under this section. The rule also would clarify that, when the commissioner's order requires the district or campus to select a specific professional service provider, the district is not required to follow competitive bidding procedures. The proposed new rule would provide parameters to be considered by the commissioner in determining whether to order alternative management or closure of a campus.

Proposed new 19 TAC §97.1067, Alternative Management of Campuses, would implement the provisions of HB 1 related to the assignment of alternative management entities to certain campuses. The proposed rule would specify the timelines and requirements for district implementation of an alternative management contract and discuss the roles that would be played by the alternative management entity. The proposed rule also would specify a district's obligation to a campus for which alternative management has been ordered.

Proposed new 19 TAC §97.1069, Providers of Alternative Campus Management, would provide for a request for qualifications (RFQ) to solicit proposals from qualified non-profit management entities to assume the alternative management of a campus. The rule would also specify that the commissioner may appoint a school district in the same education service center region to provide services as the alternative management of the campus in the same manner as a non-profit entity.

Proposed new 19 TAC §97.1071, Special Program Performance; Intervention Stages, would codify intervention and sanction processes in place under the Performance-Based Monitoring (PBM) system. The proposed rule would describe intervention activities, notification processes for PBM intervention staging, and possible interventions and/or sanctions that may be implemented under the PBM system.

Proposed new 19 TAC §97.1073, Appointment of Monitor, Conservator, or Board of Managers, would be added to establish criteria for the appointment of a monitor, conservator, management team, or board of managers by the commissioner.

Susan Barnes, associate commissioner for standards and programs, has determined that for the first five-year period the new sections are in effect there will be no fiscal implications for state and local government as a result of enforcing or administering the new sections. The proposed rule actions would add clarification of law to the required assignment of an accreditation status and implementation of sanctions and interventions under HB 1, 79th Texas Legislature, Third Called Session, 2006. The rules would assign no additional fiscal burden beyond what already is imposed by law. The TEA division responsible for program monitoring and interventions received personnel resources to implement the accreditation status and sanction requirements of HB 1.

Dr. Barnes has determined that for each year of the first five years the new sections are in effect the public benefit anticipated as a result of enforcing the new sections would be standards and procedures for determining district and charter school accreditation status. The public would be notified of the accreditation status and may assist the district in its efforts to improve its performance by addressing areas of deficiency identified by the commissioner. In addition, the proposed new rules would provide for the implementation of sanctions and interventions to improve district and campus performance that falls below minimum state standards. There will be no effect on small businesses. There is no anticipated economic cost to persons who are required to comply with the proposed new sections.

The public comment period on the proposal begins June 15, 2007, and ends July 15, 2007. Comments on the proposal may be submitted to Cristina De La Fuente-Valadez, Policy Coordination Division, Texas Education Agency, 1701 North Congress Avenue, Austin, Texas 78701, (512) 475-1497. Comments may

also be submitted electronically to *rules@tea.state.tx.us* or faxed to (512) 463-0028. All requests for a public hearing on the proposed new sections submitted under the Administrative Procedure Act must be received by the commissioner of education not more than 15 calendar days after notice of the proposal has been published in the *Texas Register*.

The new sections are proposed under the Texas Education Code, §39.071, which authorizes the commissioner to define accreditation statuses and to determine the accreditation status of each school district; TEC, §39.131, which authorizes the commissioner to determine sanctions for a district that does not satisfy accreditation criteria under TEC, §39.071, the academic performance standards under TEC, §39.072, or any financial accountability standard as determined by the commissioner; TEC, §§39.132, 39.1322-39.1324, 39.1326, and 39.1327, which authorizes the commissioner to determine sanctions for an under-performing campus; TEC, §39.1331, which authorizes the commissioner to order certain districts or campuses to acquire professional services; and TEC, §§39.134-39.136, which authorizes the commissioner to address provisions relating to powers, duties, and costs for the assignment of a monitor, conservator, management team, campus intervention team, technical assistance team, managing entity under TEC, §39.1327, or board of managers.

The new sections implement the Texas Education Code, §§39.071, 39.131, 39.132, 39.1322-39.1324, 39.1326, 39.1327, 39.133, 39.1331, and 39.134 - 39.136.

§97.1051. Definitions.

For purposes under Texas Education Code (TEC), Chapter 39, and this subchapter, the following words and terms, when used in this subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

(1) Board of trustees--The definition of this term includes a governing body of a charter holder as defined by TEC, §12.1012.

(2) Campus--An organizational unit operated by the school district that is eligible to receive a campus rating in the state accountability rating system under §97.1001 of this title (relating to Accountability Rating System), including a rating of Not Rated--Other or Not Rated--Data Integrity Issues. The definition of this term includes a charter school campus as defined by §100.1011(3)(C) of this title (relating to Definitions).

(3) Campus closure--Cessation of all instructional activity on the campus.

(A) A district ordered to close a campus may apply to the commissioner of education for approval to repurpose a building or facility formerly housing the closed campus.

(B) A building or facility that is approved for repurposing under subparagraph (A) of this paragraph must house a completely different instructional program, bear a new name, and be assigned a new campus identification number.

(C) The commissioner shall not approve the repurposing of a building or facility under subparagraph (A) of this paragraph unless:

(i) all instructional activity under the programs operated at the repurposed building or facility occurs at grade levels not previously served by the closed campus; or

(ii) at least 75% of the students previously served by the closed campus are reassigned to other campuses, the campus administrator is removed or reassigned to other campuses, and at least 75% of the instructional staff employed on the campus are removed or reassigned to other campuses.

(4) Charter school--The definition of this term has the meaning assigned by §100.1011(3) of this title. References to a charter school in TEC, Chapter 39, and rules adopted under it, shall mean either the board of trustees or the school district, as appropriate.

(5) Charter school site--The definition of this term has the meaning assigned by §100.1011(3)(D) of this title.

(6) Reconstitution--

(A) The removal or reassignment of some or all campus administrative and/or instructional personnel in accordance with at least the minimum requirements of TEC, §39.1324(b); and

(B) the implementation of a campus redesign, approved by the commissioner of education, that:

(i) provides a rigorous and relevant academic program;

(ii) provides personal attention and guidance;

(iii) promotes high expectations for all students; and

(iv) addresses comprehensive school-wide improvements that cover all aspects of a school's operations, including, but not limited to, curriculum and instruction changes, structural and managerial innovations, sustained professional development, financial commitment, and enhanced involvement of parents and the community.

(7) School district and district--The definition of these terms includes a charter operator, which is the same as a charter holder as defined by TEC, §12.1012.

§97.1053. Purpose.

(a) The provisions of Texas Education Code (TEC), Chapter 39, and this subchapter apply in the same manner to an open-enrollment charter school as to a district.

(b) The provisions of TEC, Chapter 39, and this subchapter shall be construed and applied to achieve the purposes of accreditation statuses assigned under TEC, §39.071, and the purposes of accreditation sanctions, which are to:

(1) inform the parents of students enrolled in the district, property owners in the district, general public, and policymakers of the academic, fiscal, and compliance performance of each district or campus on the standards adopted by the commissioner of education under TEC, §39.071(b) and (c), and/or listed in §97.1059 of this title (relating to Standards for All Sanction Determinations);

(2) encourage the district or campus to improve its academic, fiscal, and/or compliance performance by addressing each area of deficiency identified by the commissioner of education;

(3) enable the parents of students enrolled in the district, property owners in the district, general public, and policymakers to assist the district or campus in improving the district or campus performance by addressing each area of deficiency identified by the commissioner;

(4) encourage other districts or campuses to improve their performance so as to avoid similar action and to retain their accreditation; and

(5) improve the Texas public school system by eliminating poor academic, fiscal, and compliance performance by districts and campuses on the standards listed in §97.1059 of this title.

(c) The accreditation status assigned a district under §97.1055 of this title (relating to Accreditation Status) reflects performance under the state academic accountability rating system and financial accountability rating system beginning with the district's 2007 ratings. However, performance under these systems for earlier years shall be considered for purposes of accreditation sanctions under this subchapter. Accordingly:

(1) consideration of or failure to consider any rating of the district under §97.1055 of this title does not preclude consideration of that rating when determining accreditation sanctions under this subchapter; and

(2) except as provided by TEC, §39.1326, when determining accreditation sanctions under this subchapter, the commissioner shall consider the entire ratings history of the district and its campuses to the extent it is material.

§97.1055. Accreditation Status.

(a) General provisions.

(1) Each year, the commissioner of education shall assign to each school district an accreditation status under Texas Education Code (TEC), §39.071(b) and (c). Each district shall be assigned a status defined as follows.

(A) Accredited. Accredited means the Texas Education Agency (TEA) recognizes the district as a public school of this state that:

(i) has met the standards determined by the commissioner under TEC, §39.071(b) and (c), and specified in §97.1059 of this title (relating to Standards for All Sanction Determinations); and

(ii) has not been assigned an accreditation status of Accredited-Warned or Accredited-Probation.

(B) Accredited-Warned. Accredited-Warned means the district exhibits deficiencies in performance, as specified in subsection (b) of this section, that, if not addressed, will lead to probation or revocation of its accreditation status.

(C) Accredited-Probation. Accredited-Probation means the district exhibits deficiencies in performance, as specified in subsection (c) of this section, that must be addressed to avoid revocation of its accreditation status.

(D) Not Accredited-Revoked. Not Accredited-Revoked means the TEA does not recognize the district as a Texas public school because the district's performance has failed to meet standards adopted by the commissioner under TEC, §39.071(b) and (c), and specified in subsection (d) of this section.

(2) The commissioner shall assign the accreditation status, as defined by this section, based on the performance of each school district. This section shall be construed and applied to achieve the purposes of TEC, §39.071, which are specified in §97.1053(b) of this title (relating to Purpose).

(3) The commissioner shall revoke the accreditation status of a district that fails to meet the standards specified in this section. In the event of revocation, the purposes of the TEC, §39.071, are to:

(A) inform the parents of students enrolled in the district, property owners in the district, general public, and policymakers that the TEA does not recognize the district as a Texas public school because the district's performance has failed to meet standards adopted by the commissioner under TEC, §39.071(b) and (c), and specified in subsection (d) of this section; and

(B) encourage other districts to improve their performance so as to retain their accreditation.

(4) Unless revised as a result of investigative activities by the commissioner as authorized under TEC, Chapter 39, or other law, an accreditation status remains in effect until replaced by an accreditation status assigned for the next school year. An accreditation status shall be revised within the school year when circumstances require such revision in order to achieve the purposes of TEC, §39.071.

(5) An accreditation status will be withheld pending completion of any appeal or review of an academic accountability rating, a financial accountability rating, or other determination by the commissioner, but only if such appeal or review is:

(A) specifically authorized by commissioner rule;

(B) timely requested under and in compliance with such rule; and

(C) applicable to the accreditation status under review.

(b) Determination of Accredited-Warned status.

(1) A district shall be assigned Accredited-Warned status if, beginning with its 2007 rating, the district is assigned:

(A) for two consecutive school years, an academic accountability rating of Academically Unacceptable under §97.1001 of this title (relating to Accountability Rating System);

(B) for two consecutive school years, a financial accountability rating of Substandard Achievement or Suspended--Data Quality under §109.1002 of this title (relating to Financial Accountability Ratings);

(C) for two consecutive school years, any one of the ratings referenced in subparagraphs (A) and (B) of this paragraph; or

(D) for one school year, a combination of ratings referenced in both subparagraphs (A) and (B) of this paragraph.

(2) Notwithstanding the district's performance under paragraph (1) of this subsection, a district shall be assigned Accredited-Warned status if the commissioner determines this action is reasonably necessary to achieve the purposes of TEC, §39.071. Such action is generally required by the following circumstances:

(A) to an extent established under subsection (e) of this section, the district has failed to comply with requirements related to:

(i) the integrity of assessment or financial data used to measure performance under TEC, Chapter 39 or 42, and rules implementing those chapters;

(ii) the reporting of data under TEC, §42.006, and §61.1025 of this title (relating to Public Education Information Management System (PEIMS) Data and Reporting Standards);

(iii) other reports required by state or federal law or court order;

(iv) awarding high school graduation under TEC, §28.025; or

(v) any applicable requirement under TEC, §7.056(e)(3)(C)-(I); or

(B) after investigation under TEC, §39.074 or §39.075, the commissioner finds:

(i) the district's programs monitored under §97.1005 of this title (relating to Performance-Based Monitoring Analysis System) exhibit serious or persistent deficiencies that, if not addressed, may lead to probation or revocation of the district's accreditation; or

(ii) the district otherwise exhibits serious or persistent deficiencies that, if not addressed, may lead to probation or revocation of the district's accreditation.

(3) Notwithstanding paragraph (2) of this subsection, a district shall be assigned Accredited-Warned status if the commissioner determines this action is reasonably necessary to achieve the purposes of TEC, §39.071.

(c) Determination of Accredited-Probation status.

(1) A district shall be assigned Accredited-Probation status if, beginning with its 2007 rating, the district is assigned:

(A) for three consecutive school years, an academic accountability rating of Academically Unacceptable under §97.1001 of this title;

(B) for three consecutive school years, a financial accountability rating of Substandard Achievement or Suspended--Data Quality under §109.1002 of this title;

(C) for three consecutive school years, any one of the ratings referenced in subparagraphs (A) and (B) of this paragraph; or

(D) for two consecutive school years, a combination of ratings referenced in both subparagraphs (A) and (B) of this paragraph.

(2) Notwithstanding the district's performance under paragraph (1) of this subsection, a district shall be assigned Accredited-Probation status if the commissioner determines this action is reasonably necessary to achieve the purposes of TEC, §39.071. Such action is generally required by the following circumstances:

(A) to an extent established under subsection (e) of this section, the district has failed to comply with requirements related to:

(i) the integrity of assessment or financial data used to measure performance under TEC, Chapter 39 or 42, and rules implementing those chapters;

(ii) the reporting of data under TEC, §42.006, and §61.1025 of this title;

(iii) other reports required by state or federal law or court order;

(iv) awarding high school graduation under TEC, §28.025; or

(v) any applicable requirement under TEC, §7.056(e)(3)(C) - (I); or

(B) after investigation under TEC, §39.074 or §39.075, the commissioner finds:

(i) the district's programs monitored under §97.1005 of this title exhibit serious or persistent deficiencies that, if not addressed, may lead to revocation of the district's accreditation; or

(ii) the district otherwise exhibits serious or persistent deficiencies that, if not addressed, may lead to revocation of the district's accreditation.

(3) Notwithstanding paragraph (2) of this subsection, a district shall be assigned Accredited-Probation status if the commissioner determines this action is reasonably necessary to achieve the purposes of TEC, §39.071.

(d) Determination of Not Accredited-Revoked status; Revocation of accreditation.

(1) The accreditation of a district shall be revoked if, beginning with its 2007 rating, the district is assigned:

(A) for four consecutive school years, an academic accountability rating of Academically Unacceptable under §97.1001 of this title;

(B) for four consecutive school years, a financial accountability rating of Substandard Achievement or Suspended--Data Quality under §109.1002 of this title;

(C) for four consecutive school years, any one of the ratings referenced in subparagraphs (A) and (B) of this paragraph; or

(D) for three consecutive school years, a combination of ratings referenced in both subparagraphs (A) and (B) of this paragraph.

(2) A district shall have its accreditation revoked if, notwithstanding its performance under paragraph (1) of this subsection, the commissioner determines this action is reasonably necessary to achieve the purposes of TEC, §39.071. Such action is generally required by the following circumstances:

(A) to an extent established under subsection (e) of this section, the district has failed to comply with requirements related to:

(i) the integrity of assessment or financial data used to measure performance under TEC, Chapter 39 or 42, and rules implementing those chapters;

(ii) the reporting of data under TEC, §42.006, and §61.1025 of this title;

(iii) other reports required by state or federal law or court order;

(iv) awarding high school graduation under TEC, §28.025; or

(v) any applicable requirement under TEC, §7.056(e)(3)(C) - (I); or

(B) after investigation under TEC, §39.074 or §39.075, the commissioner finds:

(i) the district's programs monitored under §97.1005 of this title exhibit serious or persistent deficiencies that require revocation of the district's accreditation; or

(ii) the district otherwise exhibits serious or persistent deficiencies that require revocation of the district's accreditation.

(3) Notwithstanding paragraph (2) of this subsection, a district's accreditation shall be revoked if the commissioner determines this action is reasonably necessary to achieve the purposes of TEC, §39.071.

(4) The commissioner's decision to revoke a district's accreditation may be appealed under §97.1037 of this title (relating to Record Review of Certain Decisions). If the decision is sustained on appeal, the commissioner shall appoint a management team or board of managers to bring to closure the district's operation of the public school.

(e) Legal compliance. In addition to the district's performance as measured by ratings under §97.1001 and §109.1002 of this title, the accreditation status of a district is determined by its compliance with the statutes and rules specified in TEC, §39.071(b)(2). Notwithstanding satisfactory or above satisfactory performance on other measures, a district's accreditation status may be assigned based on its legal com-

pliance alone, to the extent the commissioner determines necessary. In making this determination, the commissioner:

(1) shall assign the accreditation status that is reasonably calculated to accomplish the applicable provisions specified in §97.1053(b) of this title;

(2) may impose, but is not required to impose, an accreditation sanction under this subchapter in addition to assigning a status under paragraph (1) of this subsection; and

(3) shall lower the status assigned and/or impose additional accreditation sanctions as necessary to achieve compliance with the statutes and rules specified in TEC, §39.071(b)(2).

(f) Required notification of Accredited-Warned or Accredited-Probation status.

(1) A district assigned an accreditation status of Accredited-Warned or Accredited-Probation shall notify the parents of students enrolled in the district and property owners in the district as specified by this subsection.

(2) The district's notice must contain information about the accreditation status, the implications of such status, and the steps the district is taking to address the areas of deficiency identified by the commissioner. The district's notice shall use the format and language determined by the commissioner.

(3) Notice under this subsection must:

(A) not later than 30 calendar days after the accreditation status is assigned, appear on the home page of the district's website, with a link to the notification required by paragraph (2) of this subsection, and remain until the district is assigned the Accredited status; and

(B) appear in the newspaper with the greatest circulation in the district for three consecutive days as follows:

(i) from Sunday through Tuesday of the second week following assignment of the status; or

(ii) if the newspaper is not published from Sunday through Tuesday, then for three consecutive issues of the newspaper beginning the second week following assignment of the status; or

(C) not later than 30 calendar days after the status is assigned, be sent by first class mail addressed individually to each parent of a student enrolled in the district and each property owner in the district.

(4) A district required to act under this subsection shall send the following to the TEA via certified mail, return receipt requested:

(A) the universal resource locator (URL) for the link required by paragraph (3)(A) of this subsection; and

(B) copies of the notice required by paragraph (3)(B) of this subsection showing dates of publication, or a paid invoice showing the notice content and its dates of publication; or

(C) copies of the notice required by paragraph (3)(C) of this subsection and copies of all mailing lists and postage receipts.

§97.1057. Accreditation Sanctions.

(a) The provisions of Texas Education Code (TEC), Chapter 39, and this subchapter shall be construed and applied to achieve the purposes of accreditation sanctions, which are specified in §97.1053 of this title (relating to Purpose).

(b) If the commissioner of education finds that a district or campus does not satisfy the accreditation criteria under TEC, §39.071, the academic performance standards under TEC, §39.072 or §39.073, or any financial accountability standard as determined by the commissioner, the commissioner may lower the district's accreditation status, academic accountability rating, or financial accountability rating, as applicable, and take appropriate action under this subchapter.

(c) Regardless of whether the commissioner lowers a district's status or rating under subsection (b) of this section, the commissioner may take action under this section if the commissioner determines that the action is necessary to improve any area of performance by the district or campus.

(d) Subject to §97.1035 of this title (relating to Procedures for Accreditation Sanctions), once the commissioner takes action under this subchapter, the commissioner may impose on the district any other sanction under this subchapter, singly or in combination, to the extent the commissioner determines is reasonably required to achieve the purposes specified in §97.1053 of this title.

(e) In determining whether to impose a particular sanction under this subchapter, the commissioner may consider the costs and logistical concerns of the district, but shall give primary consideration to the best interest of the district's students. The sanction selected shall be reasonably calculated to address the district's or campus' deficiencies immediately or within a reasonable time, in the best interest of its present and future students. The following shall be considered as being contrary to the best interests of the district's students:

(1) inefficient or ineffectual use of district funds or property;

(2) failure to adequately account for funds; and

(3) receipt of a substantial over-allocation of funds based on false or misleading information from the district as it relates to recovery under TEC, §42.258.

§97.1059. Standards for All Accreditation Sanction Determinations.

(a) The commissioner of education shall impose district and campus accreditation sanctions under this subchapter individually or in combination as the commissioner determines necessary to achieve the purposes identified in §97.1053 of this title (relating to Purpose).

(b) In making a determination under subsection (a) of this section, the commissioner shall consider the seriousness, number, extent, and duration of deficiencies identified by the Texas Education Agency (TEA), and shall impose one or more accreditation sanctions on a district as needed to address:

(1) each material deficiency identified by the TEA through its systems for district and campus accountability, including:

(A) an accreditation status under §97.1055 of this title (relating to Accreditation Status);

(B) an academic accountability rating under §97.1001 of this title (relating to Accountability Rating System);

(C) a financial accountability rating under §109.1002 of this title (relating to Financial Accountability Ratings) or a financial audit or investigation;

(D) program effectiveness under §97.1071 of this title (relating to Special Program Performance; Intervention Stages) or other law;

(E) the results of a special accreditation investigation under Texas Education Code, §39.075;

(F) the results of an investigative report under §97.1033 of this title (relating to Informal Review of Preliminary Investigative Report; Final Investigative Report); complaint investigation; special

education due process hearing; or data integrity investigation, including an investigation of assessment or financial data; or

(G) other information related to subparagraphs (A) - (F) of this paragraph.

(2) any ongoing failures to address deficiencies previously identified or patterns of recurring deficiencies;

(3) any lack of district responsiveness to, or compliance with, current or prior interventions or sanctions; and

(4) any substantial or imminent harm presented by the deficiencies of the district or campus to the welfare of its students or to the public interest.

(c) If the commissioner identifies a district and one or more of its campuses for accreditation sanction under subsection (a) of this section, the commissioner may elect to combine activities to be undertaken at the district and campus levels as needed to achieve the purposes of each sanction.

(d) When making any campus-level determination under this subchapter, the commissioner shall also consider the district-level performance of the district on applicable academic, fiscal, and compliance standards.

§97.1061. Technical Assistance Team Campuses.

(a) The commissioner of education will annually assign a technical assistance team to a campus rated Academically Acceptable in the state academic accountability rating system if that campus would be rated Academically Unacceptable using the accountability standards for the subsequent year. The commissioner may waive this requirement to assign a technical assistance team under standards adopted in the applicable annual accountability manual in §97.1001 of this title (relating to Accountability Rating System).

(b) The technical assistance team assigned pursuant to subsection (a) of this section will assist the campus in executing a school improvement plan and any other school improvement strategies the commissioner determines appropriate.

(c) For those campuses subject to the requirements of Texas Education Code (TEC), §11.253, the technical assistance team shall be composed of the members of the campus-level planning and decision-making committee required under TEC, §11.251 and §11.253, and shall include an additional member with the knowledge and ability to provide technical assistance in the area(s) subject to improvement planning. The additional member may be a member of the district-level planning and decision-making committee required under TEC, §11.251 and §11.252, who is not assigned to the campus or may be another individual with the requisite knowledge necessary to promote campus improvement.

(d) For those campuses not subject to TEC, §11.253, a technical assistance team shall include representative professional staff from the campus, parents of students enrolled in the campus, a business representative, community members, and an additional member with the knowledge and ability to provide technical assistance in the area(s) subject to improvement planning.

(e) The commissioner may review and approve the final membership of a technical assistance team assigned under TEC, §39.1322, and this section.

§97.1063. Campus Intervention Team; Reconstitution.

(a) If a campus is rated Academically Unacceptable in the state academic accountability rating system for the current school year, the commissioner of education shall assign a campus intervention team (CIT) under Texas Education Code (TEC), §39.1322 and §39.1323. The duties and responsibilities of the CIT will be based on the reasons for the campus' Academically Unacceptable rating.

(1) In assigning a CIT, the commissioner will offer the school district an opportunity to recommend CIT members under procedures established by the Texas Education Agency (TEA).

(A) If the district does not recommend CIT members under TEA procedures, the commissioner will assign a CIT without such input.

(B) If the commissioner does not approve the CIT membership recommendation by the district, the commissioner will assign the CIT members.

(2) If the district does not implement the school improvement plan or the recommendations of the CIT, the commissioner shall order the reconstitution of the campus in accordance with TEC, §39.1324.

(b) The principal of a campus assigned a CIT under subsection (a) of this section, or any person employed to replace that principal, shall participate in and complete the program requirements of the School Leadership Pilot Program (SLPP). The district shall be responsible for any costs associated with participation in the SLPP, such as travel, lodging, or extra duty pay.

(1) Participation in the SLPP shall begin not later than October 1 of the current school year.

(2) All program requirements of the SLPP shall be completed within one year of enrolling in the program.

(c) If a campus is rated Academically Unacceptable under the state academic accountability rating system for two consecutive school years, including the current school year, the campus shall be reconstituted under procedures developed by the TEA, and the CIT will continue to be assigned under TEC, §39.1324.

(1) A campus ordered to reconstitute shall use the current school year to plan the reconstitution, with the assistance of the district and CIT, and shall open the subsequent school year as a reconstituted campus regardless of the academic accountability rating assigned to the campus in that school year.

(A) The CIT shall decide which educators may be retained at the campus when it opens for the subsequent school year.

(B) A principal who has been employed by the campus in that capacity during the full two-year period described by this subsection may not be retained at the campus when it opens for the subsequent school year unless, in accordance with TEC, §39.116, the school district decides to retain the principal based on a demonstrated pattern of significant academic improvement by students enrolled at the campus.

(C) A teacher of a subject assessed by an assessment instrument under TEC, §39.023, may be retained for the subsequent school year only if the CIT determines that a pattern exists of significant academic improvement by students taught by the teacher.

(D) If an educator is not retained, the educator may be assigned to another position in the district when the district opens for the subsequent school year.

(2) The TEA may assign a monitor, conservator, management team, or board of managers to the campus in order to ensure the implementation of its school improvement and reconstitution plan.

(3) If the campus does not implement the school improvement and reconstitution plan or the recommendations of the CIT, the TEA may order alternative management or campus closure under

§97.1065 of this title (relating to Campus Closure or Alternative Management).

(d) If a campus is rated Academically Unacceptable under the state academic accountability rating system for the school year after reconstitution is required to be implemented under subsection (c) of this section, the commissioner:

(1) shall review the district's implementation of the school improvement and reconstitution plan in accordance with TEC, §39.1324; and

(2) may order alternative management or campus closure under §97.1065 of this title based on this review and on any other relevant information.

(e) The commissioner shall order alternative management or campus closure under §97.1065 of this title when the campus has failed to implement recommendations of the CIT or terms of the school improvement and reconstitution plan.

§97.1065. Campus Closure or Alternative Management.

(a) The commissioner of education shall order alternative management or closure of a campus as provided in this section, if:

(1) the campus is rated Academically Unacceptable under the state academic accountability rating system for the second consecutive school year after reconstitution is required to be implemented under §97.1063 of this title (relating to Campus Intervention Team; Reconstitution); or

(2) such action is required under §97.1063(e) of this title.

(b) In combination with action under this section, the commissioner may:

(1) impose a campus accreditation sanction under Texas Education Code (TEC), §39.132;

(2) take action under any provision of TEC, Chapters 12 or 39; and/or

(3) require the district to purchase professional services under TEC, §39.1331.

(A) The commissioner's order may require the district or campus to:

(i) select an external auditor, data quality expert, professional authorized to monitor district assessment instrument administration, or curriculum or program expert; or

(ii) provide for the appropriate training of district staff or board of trustees members in the case of a district, or campus staff in the case of a campus.

(B) If the commissioner's order requires the district or campus to select a specific professional service provider, the district is exempt from following competitive bidding procedures before executing the contract.

(c) The commissioner shall order alternative management of a campus under this section and shall require the campus to remain open, when:

(1) the commissioner determines that alternative management has a reasonable expectation of producing an Academically Acceptable or better campus rating in the academic accountability rating system within three rating cycles of assignment of the alternative management service provider under §97.1067 of this title (relating to Alternative Management of Campuses); and

(2) an alternative management service provider with the necessary skills and required expertise is available under §97.1069 of this title (relating to Providers of Alternative Campus Management).

(d) The commissioner shall grant the campus a one-year waiver of alternative management under this section and instead require the district to contract for appropriate technical assistance under TEC, §39.1327(c)(2), if the commissioner:

(1) determines that the basis for assigning a rating of Academically Unacceptable under the state academic accountability rating system is limited to a specific condition that may be remedied with targeted technical assistance;

(2) finds that the targeted technical assistance proposed by the district has significant potential for success in remedying the deficiencies of the district; and

(3) approves the contract for targeted technical assistance.

(e) The commissioner shall order closure of the campus when action is required under this section and:

(1) subsection (c) or (d) of this section does not apply;

(2) the district fails to enter into a contract for alternative management under §97.1067 of this title as required by §97.1067 of this title; or

(3) the commissioner does not approve the contract for alternative management under §97.1067 of this title.

(f) The commissioner shall order closure of a campus when alternative management of the campus was ordered under this section and:

(1) the district resumed operation of the campus under TEC, §39.1327(h); and

(2) for the school year immediately following resumption of operations, the campus is rated Academically Unacceptable under the state academic accountability rating system.

(g) An order proposing action under this section may be appealed only as provided by §97.1037 of this title (relating to Record Review of Certain Decisions).

§97.1067. Alternative Management of Campuses.

(a) By January 1 of the school year in which alternative management of a campus is ordered under §97.1065 of this title (relating to Campus Closure or Alternative Management), the school district shall:

(1) execute a contract in compliance with this section; and

(2) relinquish control over the campus to a service provider approved under §97.1069 of this title (relating to Providers of Alternative Campus Management).

(b) A contract under this section must be executed by the district and the service provider and must:

(1) relinquish all authority to perform the duties and responsibilities of a principal under Texas Education Code (TEC), §11.202(b)(1) - (6), with respect to the campus;

(2) comply with TEC, §39.1327(g) - (i); this section; and the requirements and performance measures established by the Texas Education Agency (TEA) under §97.1069 of this title;

(3) provide for the creation, maintenance, retention, and transfer of all public records concerning the campus;

(4) include provisions governing liability for damages, costs, and other penalties for acts or omissions by the service provider, including failure to comply with federal or state laws;

(5) provide for termination of the contract if:

(A) the campus is rated Academically Acceptable under the state academic accountability rating system for two consecutive school years; or

(B) the commissioner of education orders campus closure under §97.1065(f) of this title;

(6) specify additional roles or responsibilities assumed by the service provider, if any;

(7) be approved by written resolution of the district's board of trustees; and

(8) be approved in writing by the commissioner.

(c) The service provider may perform the duties and responsibilities of a principal, and in addition may make requests and recommendations to the district concerning all aspects of campus administration, including personnel and budget decisions.

(1) If a request is denied or a recommendation is not implemented by the district, the service provider shall report to the TEA both its request or recommendation and the district's action in response.

(2) The commissioner may implement additional sanctions under this subchapter and consider such reports under §97.1065 of this title.

(d) The funding for the campus must be not less than the funding of the other campuses operated by the district on a per-student basis so that the service provider receives at least as much funding as the campus would otherwise have received. The district must continue to support:

(1) campus maintenance and operations;

(2) transportation;

(3) food services;

(4) extracurricular activities;

(5) central office support services;

(6) state assessment administration; and

(7) similar operational expenses of the campus.

(e) A campus operated by a service provider under this section remains a campus of the district. Educators and staff assigned to work at the campus are district employees for all purposes. The campus is not subject to TEC, §11.253.

(f) A district subject to this section shall comply fully with TEA requests for information for the purpose of evaluating implementation of the contract, student performance, and management of the campus.

(g) A district that violates the terms of its contract under this section is subject to further sanctions under this subchapter.

§97.1069. Providers of Alternative Campus Management.

(a) Each school year, the Texas Education Agency (TEA) will issue a request for qualifications (RFQ) to solicit proposals from qualified non-profit management entities to assume the management of campuses identified for sanction under §97.1067 of this title (relating to Alternative Management of Campuses).

(1) To be approved as a provider of alternative campus management services, a non-profit entity must meet the requirements of Texas Education Code (TEC), §39.1327, and any additional qualifications and procedural requirements specified by the TEA in the RFQ.

(2) The commissioner of education may appoint a school district in the same education service center region as the campus to provide alternative management services under this section. A district appointed under this subsection shall assume management of the campus in the same manner as a non-profit entity.

(b) Contact information for each approved provider of alternative campus management services will be posted to the TEA website. The TEA will notify approved providers before posting the providers' information to the website.

(c) In addition to any action by the district on the contract, a service provider failing to comply with the terms of a contract under this section, or to perform services as specified in the RFQ, shall be removed from the TEA list of approved service providers.

(d) A service provider shall comply fully and promptly with TEA requests for information for the purpose of evaluating implementation of the contract, student performance, and management of the campus.

§97.1071. Special Program Performance; Intervention Stages.

(a) The commissioner of education shall assign a school district to an intervention stage based on performance levels under §97.1005 of this title (relating to Performance-Based Monitoring Analysis System) according to the following general criteria:

(1) the degree to which the district's performance reflects a need for intervention, as indicated by the seriousness, number, extent, and duration of the student performance, program effectiveness, and/or program compliance deficiencies identified by the Texas Education Agency (TEA);

(2) a comparison of the district's performance to aggregated state performance and to the performance of other districts;

(3) the availability of state and regional resources to intervene in all districts exhibiting a comparable need for intervention; and

(4) the length of time the performance standard has been in place and the length of time the district has exhibited deficiencies under the standard.

(b) In addition to performance levels determined under §97.1005 of this title, the commissioner may consider any other applicable information, such as:

(1) complaints investigation results;

(2) special education due process hearing decisions;

(3) data validation activities;

(4) integrity of assessment or financial data; and

(5) longitudinal intervention history.

(c) The standards used to assign districts to specific intervention stages under this section are established annually by the commissioner and communicated to all school districts.

(d) The commissioner may use graduated stages of intervention to address student performance, program effectiveness, and/or data quality deficiencies referenced in §97.1005 of this title. In addition to any sanction authorized by Texas Education Code (TEC), Chapter 39, Subchapter G, such intervention may require a district to implement and/or participate in:

(1) focused analysis of district data;

(2) required district review of program effectiveness;

(3) required public meetings;

(4) focused compliance reviews conducted by review teams established by the TEA;

(5) on-site reviews; and/or

(6) continuous improvement planning.

(e) The commissioner shall notify each district selected for intervention under this section via the Intervention Stage and Activity Manager (ISAM) on the TEA secure website.

(1) The TEA shall notify districts that intervention stages have been posted to ISAM by:

(A) posting a "To the Administrator Addressed" letter on the TEA web page for correspondence; or

(B) sending a "To the Administrator Addressed" letter via electronic mail or first-class mail.

(2) It is the district's obligation to access the correspondence by:

(A) subscribing to the listserv for "To the Administrator Addressed Correspondence;" and

(B) accessing the ISAM system as directed to retrieve intervention instructions and information.

(f) Intervention actions taken under this section are intended to assist the district in raising its performance and/or achieving compliance under §97.1005 of this title and do not preclude or substitute for a sanction under another provision of this subchapter.

(1) The level of intervention selected under this section does not reflect any decision on, or consideration of, the need for other sanctions.

(2) A decision to impose other sanctions shall be based on the accreditation and compliance performance of the district, as determined under §97.1035 of this title (relating to Procedures for Accreditation Sanctions) and this subchapter, and not on the level of intervention chosen under this section.

(g) Intervention actions taken under this section do not preclude or substitute for other responses to or consequences of program ineffectiveness or noncompliance identified by the TEA, such as:

(1) required fiscal audit of specific program(s) and/or of the district, paid for by the district;

(2) required submission of improvement and/or corrective action plan(s), including the provision of compensatory services as appropriate, paid for by the district;

(3) expanded oversight including, but not limited to, frequent follow-up contacts with the district, submission of documentation verifying implementation of intervention activities and/or an improvement plan; and submission of district/program data;

(4) public release of monitoring review findings;

(5) denial of requests under TEC, §7.056 and/or §12.114;

(6) reduction, suspension, redirection, or withholding of program funds;

(7) lowering of the special education monitoring status of the district; and/or

(8) lowering of the district's accreditation status, academic accountability rating, and/or financial accountability rating.

(h) As a system safeguard, the TEA will conduct desk review or on-site data verification activities through a random or other means of selection to verify system effectiveness and/or district implementation of monitoring requirements, including, but not limited to, accuracy of data reporting, implementation of intervention activities, implementation of plans for improvement or correction, and accuracy of findings made through the performance-based monitoring system process.

§97.1073. Appointment of Monitor, Conservator, or Board of Managers.

(a) The commissioner of education shall appoint a monitor, conservator, management team, or board of managers whenever such action is required, as determined by this section. Action under any other section of this subchapter is not a prerequisite to acting under this section.

(b) The commissioner shall appoint a monitor under Texas Education Code (TEC), §39.131(a)(6) when:

(1) the deficiencies identified under §97.1059 of this title (relating to Standards for All Accreditation Sanction Determinations) require a monitor to participate in and report to the commissioner on the activities of the district's board of trustees and superintendent;

(2) the deficiencies identified under §97.1059 of this title are not of such severity or duration as to require direct Texas Education Agency (TEA) oversight of district operations;

(3) the district has been responsive to and generally compliant with previous commissioner sanctions and TEA interventions; and

(4) stronger intervention is not required to prevent substantial or imminent harm to the welfare of the district's students or to the public interest.

(c) The commissioner shall appoint a conservator under TEC, §39.131(a)(7) and §39.135, or a management team under TEC, §39.131(a)(8) and §39.135, when:

(1) the nature or duration of the deficiencies require that the TEA directly oversee the operations of the district in the area(s) of deficiency;

(2) the district has not been responsive to or compliant with TEA intervention requirements; or

(3) such intervention is needed to prevent substantial or imminent harm to the welfare of the district's students or to the public interest.

(d) The decision whether to appoint a conservator or management team under subsection (c) of this section shall be based solely on logistical concerns, including the competencies required and the volume of work involved. Selecting a management team rather than a conservator does not reflect on the severity of the deficiencies to be addressed.

(e) The commissioner shall appoint a board of managers under TEC, §39.136 and §39.131(a)(9) or §39.1324(c), as applicable, when:

(1) sanctions under subsection (b) or (c) of this section have been ineffective to achieve the purposes identified in §97.1035 of this title (relating to Procedures for Accreditation Sanctions);

(2) the commissioner has initiated proceedings under §97.1037 of this title (relating to Record Review of Certain Decisions) to close or annex the district;

(3) the commissioner has initiated proceedings under §97.1037 of this title to close a campus, and such intervention is needed to cease operations of the campus; or

(4) such intervention is needed to prevent substantial or imminent harm to the welfare of the district's students or to the public interest.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

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Cristina De La Fuente-Valadez
Director, Policy Coordination
Texas Education Agency
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For further information, please call: (512) 475-1497

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CHAPTER 100. CHARTERS

SUBCHAPTER AA. COMMISSIONER'S RULES CONCERNING OPEN-ENROLLMENT CHARTER SCHOOLS

DIVISION 3. CHARTER SCHOOL FUNDING AND FINANCIAL OPERATIONS

19 TAC §100.1041

The Texas Education Agency (TEA) proposes an amendment to §100.1041, concerning open-enrollment charter schools. The section addresses charter school funding. The proposed amendment would establish criteria for review of a request for a charter holder to return over-allocated funds.

Current 19 TAC §100.1041(e) requires an open-enrollment charter holder to return an over-allocation of funds within 30 days of a request by the commissioner. In some instances, such a request could potentially result in financial closure of the open-enrollment charter school.

The proposed amendment to 19 TAC §100.1041 would add new language in subsection (e) to establish criteria for determining whether a request to return over-allocated funds would cause financial closure of an open-enrollment charter school. The proposed amendment would require the commissioner to initiate proceedings to revoke the charter under 19 TAC §100.1022, Standards for Adverse Action on an Open-Enrollment Charter, if the charter holder cannot continue operating the open-enrollment charter school due to complying with the request to return the over-allocation.

David Anderson, general counsel, has determined that for the first five-year period the amendment is in effect there will be no fiscal implications for state and local government as a result of enforcing or administering the amendment. The proposed amendment would add clarification related to certain procedural due process activities available to an open-enrollment charter school related to a record review of a request to return over-allocated funds. The proposal is in alignment with requirements in current law and does not create any additional, significant financial burden to the TEA. Funds were provided to the TEA by HB 1.

Mr. Anderson has determined that for each year of the first five years the amendment is in effect the public benefit anticipated as a result of enforcing the amendment will be that a charter holder is afforded appropriate review of a request to return an over-allocation of funds and would establish criteria and procedures for conducting such reviews. There will be no effect on small businesses. There is no anticipated economic cost to persons who are required to comply with the proposed amendment.

The public comment period on the proposal begins June 15, 2007, and ends July 15, 2007. Comments on the proposal may be submitted to Cristina De La Fuente-Valadez, Policy Coordination Division, Texas Education Agency, 1701 North Congress Avenue, Austin, Texas 78701, (512) 475-1497. Comments may also be submitted electronically to *rules@tea.state.tx.us* or faxed to (512) 463-0028. All requests for a public hearing on the proposed amendment submitted under the Administrative Procedure Act must be received by the commissioner of education not more than 15 calendar days after notice of the proposal has been published in the *Texas Register*.

The amendment is proposed under the Texas Education Code, §12.106, which authorizes the commissioner to adopt rules to provide and account for state funding of open-enrollment charter schools; TEC, §12.115 and §12.116, which authorizes the commissioner to adopt procedures and to modify, place on probation, revoke, or deny renewal of the charter of an open-enrollment charter school under certain circumstances; TEC, §39.076, which authorizes the agency to adopt written procedures for conducting on-site investigations; and TEC, §42.258, which authorizes the agency to recover overallocated funds received by a school district or open-enrollment charter school.

The amendment implements the Texas Education Code, §§12.106, 12.115, 12.116, 39.076, and 42.258.

§100.1041. State Funding.

(a) Funding formula elements. A charter school is entitled to funding from both tiers of the Foundation School Program (FSP) in accordance with the funding formulas for school districts pursuant to Texas Education Code (TEC), Chapter 42.

(1) Tier I program allocations are determined by substituting the statewide average adjusted allotment in place of the district's calculated adjusted allotment. The state average adjusted allotment takes into account the cost of education index and the small, mid-size, and sparsity adjustments specified in TEC, §§42.102, 42.103, 42.104, and 42.105. It is computed by dividing the state total cost for the regular education program by the number of students in the state counted in attendance in a regular education program in accordance with TEC, §42.101.

(2) An allocation for the guaranteed yield allotment for Tier II of the FSP is determined by substituting a statewide average enrichment tax rate in place of the district's calculated enrichment tax rate (DTR) pursuant to TEC, §42.302. The state average tax rate is computed by first summing the Maintenance and Operations tax collections up to its DTR maximum limit for each district in the state and then dividing that result by the sum of all district property values as defined in TEC, §42.252.

(b) Implementation schedule. The new formula elements described in subsection (a) of this section will take effect for charter schools that begin operation in the 2001-2002 school year or later. Charter schools that report attendance that occurs prior to September

2, 2001, are considered to be in operation on September 1, 2001, and will be funded as described in House Bill 6, Section 40(b), 77th Texas Legislature, 2001. Charter schools that report no attendance that occurs prior to September 2, 2001, are considered to begin operation in the 2001-2002 school year or later, and will be funded according to subsection (a) of this section and TEC, §12.106.

(c) Tuition and fees. A charter school shall not charge tuition and shall not charge a fee except:

(1) a charter school may charge a fee listed in TEC, §11.158(a); and

(2) if authorized under §100.1201(6) of this title (relating to Voluntary Participation in State Programs), a charter holder may charge tuition for certain prekindergarten classes in compliance with TEC, §29.1531 and §29.1532.

(d) Eligibility for state funding. A charter holder is not eligible to receive state funds, including grant funds, prior to execution of its contract by the chair of the State Board of Education.

(1) If a charter holder, before or without approval for an expansion amendment under §100.1033(d) of this title (relating to Charter Amendment), extends the grade levels it serves, adds or changes the site of an instructional facility, expands its geographic boundaries, or exceeds its maximum allowable enrollment, then the charter holder is not eligible to receive state funds for the activities of the unapproved expansion of its charter school operations.

(2) A former charter holder is not eligible to receive state funds.

(e) Return of over-allocated funds.

(1) Within 30 days of receiving notice of an over-allocation and a request for refund under TEC, §42.258, a charter holder shall transmit to the Texas Education Agency (TEA) an amount equal to the requested refund. Failure to comply with a request for refund under this subsection is a material charter violation and a management company breach. Funds allocated for student attendance in a program affected by an unapproved expansion under subsection (d)(1) of this section are over allocated within the meaning of this subsection.

(2) If the charter holder fails to make the requested refund, the TEA may recover the over allocation by any means permitted by law, including, but not limited to, the process set forth in TEC, §42.258.

(3) Notwithstanding paragraph (2) of this subsection, the TEA may not garnish or otherwise recover funds actually paid to and received by a charter holder under TEC, §12.106, if:

(A) the basis of the garnishment or recovery is that:

(i) the number of students enrolled in the school during a school year exceeded the student enrollment described by the school's charter during that period; and

(ii) the school received the funds under TEC, §12.106, based on an accurate report of the school's actual student enrollment; and

(B) the school:

(i) submits to the commissioner a timely request to revise the maximum student enrollment described by the school's charter and the commissioner does not notify the school in writing of an objection to the proposed revision before the 90th day after the date on which the commissioner received the request, provided that the number of students enrolled at the school does not exceed the enrollment described by the school's request; or

(ii) exceeds the maximum student enrollment described by the school's charter only because a court mandated that a specific child enroll in that school; and

(iii) used all funds received under TEC, §12.106, to provide education services to students;

(4) Nothing in paragraph (3) of this subsection requires the agency to fund activities that are ineligible for state funding under subsection (d)(1) of this section.

(5) The charter holder may request review under §97.1037 of this title (relating to Record Review of Certain Decisions) of a request to return over-allocated funds under paragraph (1) of this subsection as follows:

(A) Within the time provided by paragraph (1) of this subsection, the charter holder shall file a request for such review accompanied by:

(i) an opinion issued by a certified public accountant (CPA) licensed by the Texas State Board of Public Accountancy, and registered as a provider of public accounting services, that complying with the request to return over-allocated funds would require the CPA to include a "going concern" notation in the annual audit report of the charter holder under Texas Education Code (TEC), §44.008, if that audit report were issued at the time the CPA's opinion letter is issued; or

(ii) a request for the TEA to determine whether complying with the request to return over-allocated funds would likely require inclusion of such a "going concern" notation.

(B) A request under subparagraph (A)(i) of this paragraph shall transmit all financial schedules, reports, or other information used by the CPA to determine that complying with the request to return over-allocated funds would likely require inclusion of a "going concern" notation.

(C) A request under subparagraph (A)(ii) of this paragraph shall transmit or tender complete access to all financial schedules, reports, and information relevant or requested to determine whether complying with the request to return over-allocated funds would likely require inclusion of a "going concern" notation as described in subparagraph (A)(i) of this paragraph.

(D) By submitting a request under subparagraph (A)(ii) of this paragraph, the charter holder agrees to the commissioner's decision whether to grant review under §97.1037 of this title.

(6) If granted by the commissioner under paragraph (5) of this subsection, a review under §97.1037 of this title of a request to return over-allocated funds under paragraph (1) of this subsection shall determine the following:

(A) whether funds have been over-allocated to the charter holder, and by what amount;

(B) whether the over-allocation was based on false or misleading information from the charter holder; and

(C) whether recovering the full amount as required would leave the charter holder sufficient revenue and net assets to appropriately serve its current and future students. In determining sufficient revenue and net assets:

(i) the over-allocation determined under subparagraph (A) of this paragraph must be fully recovered within 24 months from the date on which the determination in subparagraph (A) of this paragraph is made; and

(ii) revenue and net assets shall be insufficient if more than 20 percent of funds allocated for the education of the charter

school's current or future students will be used to recover or repay the over-allocation instead of funding educational services to those students.

(7) Following a review under paragraph (6) of this subsection, the TEA shall:

(A) recover the over-allocation, if any, under paragraph (6)(A) of this subsection by any means permitted by law, including, but not limited to, the process set forth in TEC, §42.258; and

(B) if the commissioner has determined under paragraph (6)(B) of this subsection that the over-allocation was based on false or misleading information from the charter holder and under paragraph (6)(C) that recovering the full amount as required would leave the charter holder insufficient revenue and net assets to appropriately serve its current and future students, initiate proceedings to revoke the charter under §100.1022 of this title (relating to Standards for Adverse Action on an Open-Enrollment Charter).

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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Cristina De La Fuente-Valadez
Director, Policy Coordination
Texas Education Agency
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CHAPTER 157. HEARINGS AND APPEALS SUBCHAPTER EE. REVIEW BY STATE OFFICE OF ADMINISTRATIVE HEARINGS: CERTAIN ACCREDITATION SANCTIONS

19 TAC §§157.1151, 157.1153, 157.1155, 157.1157, 157.1159, 157.1161, 115.1163, 157.1165, 157.1167, 157.1169, 157.1171, 157.1173

The Texas Education Agency (TEA) proposes new §§157.1151, 157.1153, 157.1155, 157.1157, 157.1159, 157.1161, 157.1163, 157.1165, 157.1167, 157.1169, 157.1171, and 157.1173, concerning hearings and appeals. The proposed new sections would establish provisions relating to the review of certain accreditation sanctions by the State Office of Administrative Hearings (SOAH). The proposal reflects requirements mandated by House Bill (HB) 1, 79th Texas Legislature, Third Called Session, 2006.

HB 1 requires that an opportunity for challenging the record review of accreditation sanctions be available in specified circumstances and provided by the SOAH. Proposed new 19 TAC Chapter 157, Hearings and Appeals, Subchapter EE, Review by State Office of Administrative Hearings: Certain Accreditation Sanctions, would implement these requirements as follows.

Proposed new 19 TAC §157.1151, Applicability, would establish that the subchapter is applicable to final orders issued for alternative management, closure of a school district or an open-enrollment charter school, or closure of a campus. The proposed new section would also specify final orders to which the subchapter does not apply.

Proposed new 19 TAC §157.1153, Applicability of Other Law, would provide guidance for the applicability of other laws in relation to the conduct of hearings.

Proposed new 19 TAC §157.1155, Petition for Review, would detail the requirements for an entity to file a petition for review. The proposed new section would describe the timelines and required content of the petition for review, including allegations and statement of requested relief. The proposed new section would also address failure to comply with petition review requirements and would address TEA responsibilities related to the petition.

Proposed new 19 TAC §157.1157, Standard of Review, would establish procedures for standards for review by the SOAH in relation to decisions made by the commissioner. This new section would also detail the reasons that the SOAH could reverse the decision by the commissioner.

Proposed new 19 TAC §157.1159, Scope of Review; Additional Evidence, would describe the type of additional evidence that can and cannot be submitted to the administrative law judge in addition to the agency record.

Proposed new 19 TAC §157.1161, Components of Agency Record, would detail the components of what should be included in the agency record of proceedings. These components correspond to provisions specified in proposed new 19 TAC §97.1037, Record Review of Certain Decisions.

Proposed new 19 TAC §157.1163, Proceedings Regarding Agency Record, would establish agency procedures for filing the proceedings of the agency record, including timelines and cost.

Proposed new 19 TAC §157.1165, Enforcement of Decision Pending Review, would provide the procedures for the timely implementation of the commissioner's decision.

Proposed new 19 TAC §157.1167, Expedited Review, would provide the process for conducting the review in an expedited manner, including timelines for possible pre-hearings, continuances, and dispute resolution. The proposed new section would also require the administrative law judge to issue a final order no later than the 30th calendar day after the date on which the record is finally closed.

Proposed new 19 TAC §157.1169, Conduct of Review During a Ratings Appeal, would provide procedures for the commissioner and administrative law judge for the conduct of the review during a ratings appeal under TEC, §39.301, and for submission of documents related to the ratings appeal.

Proposed new 19 TAC §157.1171, Final Decision, would provide for final resolution of the appeal and state that the decision of the administrative law judge is final and may not be appealed. The proposal would specify that an administrative law judge may not change an accreditation status or an academic or a financial accountability rating.

Proposed new 19 TAC §157.1173, Application to Charter Schools, would provide for the application of proposed new 19 TAC Chapter 157, Subchapter EE, to open-enrollment charter schools.

David Anderson, general counsel, has determined that for the first five-year period the new sections are in effect there will be no additional fiscal implications for state and local government as a result of enforcing or administering the proposed new sections. The proposed rule actions would add clarification of law related to HB 1, 79th Texas Legislature, Third Called Session,

2006, requirements. While there is no additional fiscal burden beyond what already is required by law, a district may incur costs if it elects to hire an attorney to represent them in a SOAH proceeding. The TEA may incur costs in contracting with the SOAH for these hearings.

Mr. Anderson has determined that for each year of the first five years the new sections are in effect the public benefit anticipated as a result of enforcing the new sections would be to ensure that entities are afforded appropriate review of certain accreditation sanctions and to provide guidelines for the TEA and SOAH for the conduct of such reviews. There will be no effect on small businesses. There is no anticipated economic cost to persons who are required to comply with the proposed new sections.

The public comment period on the proposal begins June 15, 2007, and ends July 15, 2007. Comments on the proposal may be submitted to Cristina De La Fuente-Valadez, Policy Coordination Division, Texas Education Agency, 1701 North Congress Avenue, Austin, Texas 78701, (512) 475-1497. Comments may also be submitted electronically to *rules@tea.state.tx.us* or faxed to (512) 463-0028. All requests for a public hearing on the proposed new sections submitted under the Administrative Procedure Act must be received by the commissioner of education not more than 15 calendar days after notice of the proposal has been published in the *Texas Register*.

The new sections are proposed under the Texas Education Code, §39.302, which authorizes the agency to establish procedures for creating an administrative record for review by the State Office of Administrative Hearings for certain decisions.

The new sections implement the Texas Education Code, §39.302.

§157.1151. Applicability.

(a) This subchapter applies only to a final order issued under §97.1037(f) of this title (relating to Record Review of Certain Decisions) that orders:

(1) alternative management of a school district campus or a charter school campus under Texas Education Code (TEC), §39.1327;

(2) closure of a school district or an open-enrollment charter school under TEC, §§39.071(c), 39.131(a), or 39.1321(c); or

(3) closure of a school district campus or charter school campus under TEC, §39.1324 or §39.1327.

(b) This subchapter does not apply to:

(1) a final order issued under §97.1037(f) of this title that orders:

(A) assignment under §97.1055 of this title (relating to Accreditation Status) of an accreditation status of Accredited-Warned or Accredited-Probation;

(B) assignment of a board of managers under TEC, §39.136 and §39.131(a)(9) or §39.1324(c); or

(C) an audit recovery from an open-enrollment charter school under §97.1037(a)(4) of this title; or

(2) a final order issued pursuant to the no-request provision specified in §97.1037(g) of this title.

§157.1153. Applicability of Other Law.

(a) A challenge under this subchapter shall be governed by the contested case procedures provided by this subchapter and Government Code, Chapter 2001, as modified by Texas Education Code, §39.302.

(b) To the extent that a provision of this subchapter conflicts with a rule or practice of the State Office of Administrative Hearings, this subchapter shall prevail.

(c) The record review conducted under §97.1037 of this title (relating to Record Review of Certain Decisions) is not governed by Government Code, Chapter 2001.

§157.1155. Petition for Review.

(a) A school district or open-enrollment charter school subject to a decision defined by §157.1151 of this title (relating to Applicability) (petitioner) may file with the Texas Education Agency (TEA) division responsible for hearings and appeals a petition for review of the decision under this subchapter not later than the 30th calendar day after the date the decision complained of is first communicated to the school district or charter school.

(1) The petition for review shall include a copy of the challenged decision and any attachments or exhibits to the decision.

(2) The petition for review shall concisely state, in numbered paragraphs:

(A) if alleging the decision was made in violation of a statutory provision, the statutory provision violated and the specific facts supporting a conclusion that the statute was violated by the decision;

(B) if alleging the decision was made in excess of the TEA's statutory authority, the TEA's statutory authority and the specific facts supporting a conclusion that the decision was made in excess of this authority;

(C) if alleging the decision was made through unlawful procedure, the lawful procedure and the specific facts supporting a conclusion that the decision was made through unlawful procedure;

(D) if alleging the decision was affected by other error of law, the law violated and the specific facts supporting a conclusion that the decision violated that law;

(E) if alleging the decision was not reasonably supported by substantial evidence considering the reliable and probative evidence in the record as a whole, each finding, inference, conclusion, or decision that was unsupported by substantial evidence in the record;

(F) if alleging the decision was arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion, each finding, inference, conclusion, or decision affected and the specific facts supporting a conclusion that each was so affected; and

(G) for each violation, error, or defect alleged under subparagraphs (A) - (F) of this paragraph, the substantial rights of the school district or charter school that were prejudiced by such violation, error, or defect.

(3) A petition for review shall further contain:

(A) a concise statement of the relief sought by the petitioner; and

(B) the name, mailing address, telephone number, and facsimile number of the petitioner's representative.

(4) A request for relief in a review under this subchapter may not be made orally or as part of the record at a prehearing conference or hearing.

(b) Failure to comply with the requirements of subsection (a) of this section shall result in dismissal of the petition for review. A peti-

tion for review may not be amended or supplemented after the deadline for filing a petition for review.

(c) The TEA division responsible for hearings and appeals shall transmit the petition for review to the State Office of Administrative Hearings with a request that it be docketed.

(d) If the TEA chooses to file an answer, the answer must be filed by the date the record is filed under §157.1163 of this title (relating to Proceedings Regarding Agency Record).

§157.1157. Standard of Review.

(a) A challenge under this subchapter shall be governed by the substantial evidence rule as provided by Government Code, §2001.174 and §2001.175, and judicial case precedents construing those provisions.

(b) The State Office of Administrative Hearings (SOAH) may not substitute its judgment for the judgment of the commissioner of education on questions committed to commissioner discretion.

(c) The SOAH may not substitute its judgment for the judgment of the commissioner on the weight to be assigned the evidence before the commissioner.

(d) The SOAH may affirm the commissioner decision in whole or in part.

(e) The SOAH shall reverse the decision if substantial rights of the school district or open-enrollment charter school have been prejudiced because the administrative findings, inferences, conclusions, or decisions of the commissioner are:

(1) in violation of a statutory provision;

(2) in excess of the commissioner's authority;

(3) made through unlawful procedure;

(4) affected by other error of law;

(5) not reasonably supported by substantial evidence considering the reliable and probative evidence in the record as a whole; or

(6) arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion.

§157.1159. Scope of Review; Additional Evidence.

(a) The administrative law judge is confined to the Texas Education Agency (TEA) record, except that the administrative law judge may receive evidence of procedural irregularities alleged to have occurred before the TEA that are not reflected in the record.

(b) A party may apply to the administrative law judge to present additional evidence of procedural irregularities alleged to have occurred before the TEA that are not reflected in the record.

(1) If the additional evidence is material to the outcome of the review, and if there were good reasons for the failure to present it in the proceeding before the TEA, the administrative law judge may order that the additional evidence be taken before the TEA on conditions determined by the administrative law judge.

(2) The commissioner of education may change the TEA findings and decision by reason of the additional evidence, and the TEA shall file the additional evidence and any changes, new findings, or decisions with the administrative law judge.

(c) The administrative law judge may not take testimony, question witnesses, administer oaths, rule on questions of evidence, or compel discovery or disclosure of evidence in any form.

§157.1161. Components of Agency Record.

The Texas Education Agency (TEA) record of proceedings shall include the following components, as specified under §97.1037 of this title (relating to Record Review of Certain Decisions):

(1) the notice of proposed order under §97.1037(b) of this title, including all information referenced in the notice under §97.1037(b)(1) of this title;

(2) the request for record review under §97.1037(c) of this title, including any request for the attendance of specific TEA staff under §97.1037(d)(3) of this title;

(3) any written correspondence made a part of the record by the TEA representative under §97.1037(d)(5) of this title;

(4) any audiotapes or similar recordings made a part of the record by the TEA representative under §97.1037(d) of this title;

(5) all audiotapes or similar recordings of the record review under §97.1037 of this title, and any recorded telephone conferences, proffers of excluded information, or other recorded proceedings before the TEA representative under §97.1037 of this title;

(6) all written information presented to the TEA representative during the record review;

(7) a description of all matters officially noticed; and

(8) the final order under §97.1037(f) of this title.

§157.1163. Proceedings Regarding Agency Record.

(a) The Texas Education Agency (TEA) shall file the original or a certified copy of the entire record of the proceeding under review not later than the 20th calendar day after the date the petition for review is filed, unless additional time is allowed by the administrative law judge.

(b) The record may be shortened by stipulation of all parties to the review proceedings. The administrative law judge may assess costs against a party who unreasonably refuses to stipulate to limit the record, unless that party is required to pay all costs of record preparation.

(c) The petitioner shall offer, and the administrative law judge shall admit, the TEA record into evidence as an exhibit.

(d) The administrative law judge may require or permit later corrections or additions to the record.

§157.1165. Enforcement of Decision Pending Review.

The pendency of a review under this subchapter does not stay or otherwise affect the enforcement of the commissioner of education decision challenged under this subchapter.

§157.1167. Expedited Review.

(a) The State Office of Administrative Hearings shall expedite its review of a challenge under this subchapter.

(b) The administrative law judge shall issue a pre-hearing order initially setting a date for closure of the record that is not later than the 30th calendar day after the date the petition for review is filed.

(c) The administrative law judge may grant a continuance of the date set in subsection (b) of this section only for good cause shown.

(d) The administrative law judge may not order a settlement conference, mediation, or other form of alternative dispute resolution.

(e) The administrative law judge shall issue a final order not later than the 30th calendar day after the date on which the record is finally closed.

§157.1169. Conduct of Review During a Ratings Appeal.

(a) A decision is final within the meaning of §157.1151(a) of this title (relating to Applicability) even if based, in part, on a rating

that may yet be appealed under Texas Education Code (TEC), 39.301. In the commissioner of education's sole discretion, the decision may be delayed or withdrawn pending the outcome of a ratings appeal under TEC, §39.301, that is timely and sufficient under applicable rules.

(b) The administrative law judge shall proceed with an expedited review under this subchapter during any ratings appeal under TEC, §39.301, and shall presume for purposes of such review that the rating will not change by reason of the appeal, unless the commissioner:

(1) withdraws the decision under subsection (a) of this section; or

(2) requests that review of the final decision be abated pending the outcome of the ratings appeal.

(c) If a rating is adjusted by the commissioner following an appeal under TEC, §39.301, the administrative law judge shall order that the adjusted rating be treated as additional evidence to be taken before the Texas Education Agency (TEA) under §157.1163 of this title (relating to Proceedings Regarding Agency Record). The TEA may change its findings and/or decision by reason of the additional evidence and shall file the additional evidence and any changes, new findings, or decisions with the administrative law judge.

§157.1171. Final Decision.

(a) The decision of the administrative law judge:

(1) must rule on each mandatory sanction listed in Texas Education Code, §39.1324;

(2) may not order a sanction or relief that the commissioner of education is not authorized to order under applicable law;

(3) may not change an accreditation status; and

(4) may not change an academic or a financial accountability rating.

(b) The decision of the administrative law judge is final and may not be appealed.

§157.1173. Application to Charter Schools.

(a) The charter of an open-enrollment charter school is automatically:

(1) revoked, void, and of no further force or effect on the effective date of a final decision by the commissioner of education ordering the charter school closed under this subchapter; and

(2) modified to remove authorization for an individual campus on the effective date of a final decision by the commissioner ordering the campus closed under this subchapter.

(b) If sanctions are imposed on an open-enrollment charter school under the procedures provided by this subchapter, a charter school is not entitled to an additional hearing relating to the modification, placement on probation, revocation, or denial of renewal of a charter as provided by Texas Education Code, Chapter 12, Subchapter D.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702225

Cristina De La Fuente-Valadez
Director, Policy Coordination
Texas Education Agency
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 475-1497

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PART 8. WINDHAM SCHOOL DISTRICT

CHAPTER 300. GENERAL PROVISIONS

19 TAC §300.1

The Windham School District (WSD) Board of Trustees (Board) proposes amendments to §300.1, Public Testimony and Comments to the Windham School District Board of Trustees. The proposed amendments are necessary to clarify procedures for public presentations and comments on topics under the jurisdiction of the WSD Board.

David McNutt, Chief Financial Officer for the Windham School District, has determined that for the first five (5) years the rule will be in effect, enforcing or administering the rule will not have foreseeable implications related to costs or revenues for state or local government.

Mr. McNutt has also determined, that for the first five (5) year period, there will not be an economic impact on persons required to comply with the rule. There will not be an effect on small or micro businesses. The anticipated public benefit, as a result of enforcing the rule, will be to provide the opportunity for public presentations and comments to the Board.

Comments should be directed to Michael P. Mondville, General Counsel, Windham School District, P.O. Box 40, Huntsville, Texas 77342, Michael.Mondville@wsdtx.org. Written comments from the general public should be received within 30 days of the publication of this rule.

The amendments are proposed under Texas Government Code, Chapter 551.

Cross Reference to Statutes: Texas Government Code, Chapter 551.

§300.1. Public Presentations [~~Testimony~~] and Comments to the Windham School District Board of Trustees.

(a) Policy. The Windham School District (WSD) Board of Trustees (Board) is committed to providing [~~provide~~] access and opportunity for public presentations and comments as provided for in this rule. [~~testimony on items that are part of the Board's posted agenda as provided for in this subsection and in subsection (b) of this section. The Board also invites public comment on issues within the jurisdiction of the Board as provided for in this subsection and in subsection (c) of this section.~~] Persons not employed by or under contract with [~~outside~~] the WSD [~~agency~~] who wish to have items placed on the Board's posted [~~Board~~] agenda, shall [~~are invited to~~] follow the procedures set forth [~~procedure~~] in subsection (h) [~~(d)~~] of this rule [~~section~~]. Public presentations [~~testimony~~] and [~~public~~] comments shall be:

(1) subject to the requirements and restrictions of subsections (b), (c), (d), (e), (f)[~~,~~] and (g) [~~and (h)~~] of this rule [~~section~~];

(2) pertinent to issues under the jurisdiction of the Board, as determined by the Board Chairman and the WSD Superintendent; and

(3) pertinent to [~~WSD~~] policies, procedures, standards[~~,~~] and rules of the WSD. Disputes [~~, while actual disputes~~] that are appropriately [~~properly~~] the subject of the appeals process for contract non-renewal or employee termination, the employee grievance system, the employee disciplinary system or comments regarding pending litigation shall be addressed through those processes.

(b) Definitions.

(1) Public presentations--presentations made by the public to the Board regarding topics posted on a Board meeting agenda that has been filed with and published by the *Texas Register* and as provided for in subsection (c) of this rule.

(2) Public comments--comments made by the public on non-posted Board agenda topics and as provided for in subsection (d) of this rule.

(c) [~~(b)~~] Public presentations. [~~testimony on posted agenda topics.~~] Persons who desire to make public presentations [~~testimony~~] to the Board on posted agenda topics shall [~~must~~] provide, on the date of the meeting, a completed registration card to onsite Board office [~~the Board's support~~] staff at least ten (10) minutes prior to the meeting's posted start time. Registration cards shall be made available at the entry to the room [~~place~~] where the Board's scheduled meeting is [~~to be~~] held. [~~and shall include blanks in which all of the following information must be disclosed:~~]

(1) Pre-registration is available for public presentations through first class mail (P.O. Box 13084, Austin Texas 78711) or email (tbcj@tdcj.state.tx.us). Pre-registration shall be received by the Board office staff no later than four (4) calendar days prior to the posted meeting date of the presentation. In addition to the information required in subsection (c)(2), pre-registration submissions shall include appropriate contact information (daytime phone number and/or email address) for the individual who is registering to speak.

(2) Registration cards and pre-registration submissions shall disclose:

(A) [~~(1)~~]the name of the person who will make the [~~making a~~] presentation;

(B) [~~(2)~~]a statement as to whether the person is being remunerated [~~reimbursed~~] for the presentation[~~,~~] and if so, by whom; and if applicable, the name of the person or entity on whose behalf the presentation will be [~~is~~] made;

(C) [~~(3)~~]a statement as to whether the presenter has registered as a lobbyist in relation [~~relationship~~] to the agenda topic being addressed [~~matter in question~~];

(D) [~~(4)~~]a reference to the agenda topic on which [~~item, that~~] the person wishes to present [~~discuss before the Board~~];

(E) [~~(5)~~]an indication as to whether the presenter will [~~wishes to~~] speak for or against the proposed agenda topic [~~item~~]; and

(F) [~~(6)~~]a statement verifying that all [~~factual~~] information that will [~~to~~] be presented is factual, [~~shall be~~] true and correct to the best of the speaker's knowledge [~~of the speaker~~].

(3) The Board Chairman shall have discretion in setting reasonable limits on the time allocated for public presentations on posted agenda topics. If several persons have registered to address the Board on the same agenda topic, it shall be within the discretion of the Board Chairman to request that those persons select a representative amongst themselves to express such remarks, or to limit their presentations to an expression of support for views previously articulated.

(4) The Board Chairman shall provide an opportunity for public presentations to occur prior to the Board taking action on the topic denoted on the presenter's registration card. If a person who is registered to speak on a posted agenda item is not present when called upon, that person's opportunity to speak prior to action being taken on such topic shall be forfeited.

(5) A presenter may submit documentation pertaining to the public presentation to the Board office staff no later than three (3) calendar days prior to the posted meeting date where the presentation is to occur. Such documentation shall then be distributed to the Board. Any documentation submitted after the above-referenced date will not be distributed to the Board until after the presentation. A minimum of 12 copies of any such documentation shall be submitted to the Board office staff or distribution will not occur.

(d) [~~(c)~~]Public comments [~~on non-posted topics~~].

(1) The Board defines its areas of jurisdiction in BP- [~~Board Policies 1.00 and~~] 2.00, which is available through [~~at~~] the Board office at the address listed in subsection (c) [~~(d)~~] of this rule [~~section~~], or on the Internet at http://www.windhamschooldistrict.org/csd/policy/. Twice a year at the second [~~first~~] and fourth regular [~~regularly~~] called meetings of the Board, [~~which are typically held in January and July,~~] an opportunity shall be provided for public comment on issues that are not part of the Board's posted agenda but are within the Board's jurisdiction [~~of the Board~~]. Special called meetings are not counted toward the requirement of this subsection.

(2) Persons who desire to make public comments to the Board at these meetings shall [~~must~~] provide, on the date of the meeting, a completed registration card to onsite Board office [~~the Board's support~~] staff at least ten (10) minutes prior to the meeting's posted start time. Registration cards shall be made available at the entry to the room [~~place~~] where the Board's scheduled meeting is [~~to be~~] held.

(3) Pre-registration is [~~also~~] available for public comments [~~individuals interested in speaking at the bi-annual public comment periods. Pre-registration must be submitted to the Board office either~~] through first class mail (P.O. Box 13084, Austin Texas 78711) or email (tbcj@tdcj.state.tx.us). Pre-registration shall be received by Board office staff[~~, and must take place~~] no earlier than the first day of the [~~even-numbered~~] month preceding the Board meeting for which the registration is intended[~~,~~] and no later than four (4) calendar [~~seven (7)~~] days prior to the posted [~~same~~] meeting date where the comments are to occur. In addition to the information required in subsection (d)(4), pre-registration submissions shall include appropriate contact information (daytime phone number and/or email address) for the individual who is registering to speak.

(4) Registration cards and pre-registration submissions shall [~~must~~] disclose [~~the following information~~]:

(A) the name of the person who will make [~~making~~] the comments [~~presentation~~];

(B) a statement as to whether the person is being remunerated [~~reimbursed~~] for the comments [~~presentation~~], and if so, by whom; and, if applicable, the name of the person or entity on whose behalf the comments will be [~~presentation is~~] made;

(C) a statement as to whether the presenter has registered as a lobbyist in relation [~~relationship~~] to the topic being addressed [~~matter in question~~];

(D) the topic on which the person shall speak and whether the person will speak for or against the topic; and

(E) a statement verifying that all [~~factual~~] information that will [~~to~~] be presented is factual, [~~shall be~~] true and correct to the best of the speaker's knowledge [~~of the speaker~~].

(5) [~~(e)~~] [~~Presentation timing.~~] The Board Chairman shall have discretion in setting reasonable limits on the time [~~to be~~] allocated for public comments [~~testimony or public comment~~]. If several persons have registered [~~wish~~] to address the Board on the same topic [~~agenda item~~], it shall be within the discretion of the Board Chairman to request that those persons select a representative amongst themselves to express such comments [~~who wish to address the same side of the issue coordinate their comments~~], or limit their comments to an expression of support for views previously articulated. [~~by persons speaking on the same side of an issue. For public testimony on posted agenda topics, the Chairman shall provide an opportunity for said testimony by a person who has submitted a registration card to occur prior to the Board taking action on the item denoted on the registration card.~~]

(6) Public comments shall be heard just prior to the conclusion of the Board meeting, with deviation from this practice within the discretion of the Board Chairman. If a person who is registered to speak on a non-posted topic is not present when called upon, that person shall be called once more following all other registered speakers. If that person is not present at that time, their opportunity to speak at that meeting shall be forfeited.

(7) Presenters may submit documentation pertaining to the public comments to the Board office staff no later than three (3) calendar days prior to the posted meeting date where the comments are to occur. Such documentation shall then be distributed to the Board. Any documentation submitted after the above-referenced date will not be distributed to the Board until after the comments. A minimum of 12 copies of any such documentation shall be submitted to the Board office staff or distribution will not occur.

[~~(d) Requests that issues be placed on an agenda. Persons outside the agency who wish to have an agenda item posted for discussion shall address their request to the Chairman, Texas Board of Criminal Justice, P.O. Box 13084, Austin, Texas 78711. Such requests should be submitted by the first day of the even-numbered month preceding the Board meeting for which the request is intended and are subject to the requirements of the registration card in subsection (b) of this section. The decision whether to calendar a matter for discussion before the full Board, a Board committee, a Board liaison, or with a designated staff member, shall be within the discretion of the Chairman.~~]

(e) [~~(f)~~]Disability accommodations [~~accommodation~~]. Persons with disabilities who have special communication or accommodation needs and who plan to attend a meeting may contact the Board office at (512) 475-3250 [~~in Austin~~]. Requests for accommodation shall [~~should~~] be made at least two (2) calendar days prior to [~~before~~] a posted meeting. The Board shall [~~will~~] make every reasonable effort to accommodate these needs.

(f) [~~(g)~~]Conduct and decorum. The Board shall [~~will~~] receive public presentations [~~testimony~~] and [~~public~~] comments as authorized by this rule [~~section~~], subject to the following additional guidelines:[~~.~~]

(1) Due to requirements of the Open Meetings Act, questions [~~Questioning of those making presentations~~] shall only occur on public presentations as defined herein (not as to public comments as defined herein) that are [~~testimony~~] associated with posted agenda topics and they shall be reserved for [~~to~~] Board members and staff recognized by the Board Chairman;

(2) Presentations and comments shall remain pertinent to the issues [~~issue~~] denoted on the registration cards [~~card~~];

(3) A presenter [~~person~~] who is determined by the Board Chairman to be disrupting a meeting shall [~~must~~] immediately cease the disruptive activity or leave the meeting room if ordered to do so by the Board Chairman; and

(4) A presenter [~~person~~] may not assign a portion of his or her allotted presentation time to another speaker.

(g) [~~(h)~~]A presenter [~~person~~] may not carry or possess a prohibited weapon (as defined in Section 46.05, Texas Penal Code), an illegal knife, a club[~~,~~] or a handgun, to include a licensed concealed handgun, during any [~~at a~~] meeting of the Board.

(h) Requests for issues to be placed on an agenda. Persons not employed by or under contract with the WSD who wish to propose an agenda item for discussion on a Board meeting shall address the request in writing to the Chairman, Windham School District Board of Trustees, P.O. Box 13084, Austin, Texas 78711. Such requests shall be titled, "Proposed Agenda Topic" and shall be submitted no later than the first day of the month preceding the Board meeting for which the request is intended. Such requests are subject to the requirements of the registration card in subsection (c) of this rule. The decision as to whether to calendar a matter for discussion before the Board, a Board committee, a Board liaison, or with a designated staff member shall be within the discretion of the Board Chairman. Public presentations on topics placed on a Board agenda, at the request of an individual, shall be in accordance with subsection (c) of this rule.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 25, 2007.

TRD-200702086
Melinda Hoyle Bozarth
General Counsel, Texas Department of Criminal Justice
Windham School District
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 463-0422

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TITLE 22. EXAMINING BOARDS

PART 14. TEXAS OPTOMETRY BOARD

CHAPTER 271. EXAMINATIONS

22 TAC §271.2

The Texas Optometry Board proposes amendments to §271.2 concerning requirements for license application. The amendment clarifies when college and optometry school transcripts must be submitted to the Board.

Chris Kloeris, executive director of the Texas Optometry Board, has determined that for the first five-year period the proposed amendment is in effect, there will be no fiscal implications for state and local governments as a result of enforcing or administering the rule.

Chris Kloeris also has determined that for each of the first five years the amendment is in effect, the public benefit anticipated is that applicants will have clear guidelines regarding the time period to submit required documents.

The amendments do not require the submission of additional documents. Therefore Mr. Kloeris has determined that there will

be no economic costs for persons who are required to comply with the amendments, including small businesses. No disparate effect is foreseen on small or micro-businesses.

Comments on the proposal may be submitted to Chris Kloeris, Executive Director, Texas Optometry Board, 333 Guadalupe Street, Suite 2-420, Austin, Texas 78701-3942. The deadline for furnishing comments is thirty days after publication in the *Texas Register*.

The amendment is proposed under the Texas Optometry Act, Texas Occupations Code, §351.151, and §351.254. No other sections are affected by the amendments.

The Texas Optometry Board interprets §351.151 as authorizing the adoption of procedural and substantive rules for the regulation of the optometric profession and §351.254 as setting the educational requirements for license as an optometrist.

§271.2. Applications.

(a) - (e) (No change.)

(f) Applications submitted by graduates of an approved college of optometry must contain a certified copy of the optometry school transcript. A license will not be issued until the applicant has submitted certified [~~Certified~~] copies of the transcript of record from preoptometry and optometry colleges attended by the applicant [~~shall accompany each application~~], which certified transcript of record shall show the total number of hours of attendance, the subjects studied, the grades or marks given, and the date of graduation of the applicant. All transcripts must be submitted to the executive director prior to the date which is one year after successful passage of the board's jurisprudence examination; otherwise, the applicant must reapply and take and pass the board's jurisprudence examination.

(g) - (i) (No change.)

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 31, 2007.

TRD-200702128
Chris Kloeris
Executive Director
Texas Optometry Board
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 305-8502

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CHAPTER 273. GENERAL RULES

22 TAC §273.8

The Texas Optometry Board proposes amendments to §273.8 concerning reinstatement of expired licenses and reexamination requirements for expired licenses. The amendments clarify the type of examination required for licenses that have expired, including therapeutic license requirements. For expired licenses where the optometrist is practicing in another state, the amendments require the applicant for reinstatement to obtain an official license verification from all states in which the optometrist is licensed, and clarifies that §351.501 of the Optometry Act applies to license reinstatements.

Chris Kloeris, executive director of the Texas Optometry Board, has determined that for the first five-year period the amendment is in effect, there will be no fiscal implications for state and local governments as a result of enforcing or administering the rule.

Chris Kloeris also has determined that for each of the first five years the amendment is in effect, the public benefit anticipated is that the agency will have access to records of any disciplinary action that the expired licensee may have received in the current states of licensure, which can be reviewed by the agency prior to a reinstatement of an expired license. The amendments will require persons applying to reinstate an expired license to submit one or more license verifications, depending on the number of states in which licensed, which typically cost $15 to $20. This cost will be incurred by individual applicants, and no disparate effect is foreseen on small or micro-businesses. The amendment clarifying the examination required for a new license when the license has expired, including therapeutic examination and education, does not change the examination currently used. Obtaining 16 hours of continuing education is estimated to cost $500. This cost will be incurred by individual applicants, and no disparate effect is foreseen on small or micro-businesses.

Comments on the proposal may be submitted to Chris Kloeris, Executive Director, Texas Optometry Board, 333 Guadalupe Street, Suite 2-420, Austin, Texas 78701-3942. The deadline for furnishing comments is thirty days after publication in the *Texas Register*.

The amendment is proposed under the Texas Optometry Act, Texas Occupations Code, §§351.151, 351.252, 351.304, 351.306, 351.308 and 351.501. No other sections are affected by the amendments.

The Texas Optometry Board interprets §351.151 as authorizing the adoption of procedural and substantive rules for the regulation of the optometric profession, §351.252 as setting the requirements for therapeutic license, §351.304 to require reexamination upon license expiration, §351.306 to allow reinstatement of an expired license if the former licensee is practicing out of state, §351.308 as setting continuing education requirements, and §351.501 as defining the conduct by applicants or licensees that allow the agency to refuse to issue a license or impose disciplinary action.

§273.8. Renewal of License.

(a) Expired license.

(1) - (3) (No change.)

(4) If a person's license has been expired for one year or longer, the person may not renew the license but may obtain a new license by taking and passing the jurisprudence exam, [~~submitting to reexamination,~~] obtaining 16 hours of board approved continuing education, and complying with the requirements and procedures for obtaining an initial license. If the person was not licensed as a therapeutic optometrist when the license expired, the person must also complete the requirements for therapeutic license in §§280.1 - 280.3 of this title prior to obtaining a new license.

(5) The board, however, may renew without examination an expired license of a person who was previously licensed in Texas, is currently licensed in another state, and has been in practice for two years immediately preceding application for renewal. The person shall be required to furnish documentation of continuous practice for the two-year period, pay the renewal fee as established by subsection (a)(3) of this title, above. The person must furnish license verifications from each state in which the person is currently or previously licensed. A license renewal under this section is subject to the same requirements of §351.501 of the Act as a license applicant.

(6) - (7) (No change.)

(b) (No change.)

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 31, 2007.

TRD-200702129
Chris Kloeris
Executive Director
Texas Optometry Board
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 305-8502

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PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 291. PHARMACIES
SUBCHAPTER A. ALL CLASSES OF PHARMACIES

The Texas State Board of Pharmacy proposes new §291.2, concerning Definitions, §291.3, concerning Required Notifications, §291.24, concerning Pharmacy Residency Programs, and §291.27, concerning Confidentiality. The Texas State Board of Pharmacy proposes amendments to §291.6, concerning Pharmacy License Fees, §291.8, concerning Return of Prescription Drugs, §291.10, concerning Pharmacy Balance Registration/Inspection, §291.18, concerning Time Limit for Filing a Complaint, §291.19, concerning Administrative Actions as a Result of a Compliance Inspection, §291.22, concerning Petition to Establish an Additional Class of Pharmacy, and §291.23, concerning Pilot or Demonstration Research Projects for Innovative Applications in the Practice of Pharmacy. The Texas State Board of Pharmacy proposes the repeal of §291.2, concerning Change of Location and/or Name, §291.3, concerning Managing Officers, §291.4, concerning Change of Ownership, §291.7, concerning Change of Pharmacist Employment, §291.12, concerning Fire or Other Disaster, §291.13, concerning Emergency Remote Pharmacy License, §291.15, concerning Notification of Theft of Loss of a Controlled Substance or a Dangerous Drug, §291.16, concerning Definitions, §291.20, concerning Remote Pharmacy Services, §291.21, concerning Notification to Consumers, §291.25, concerning Pharmacies Compounding Non-sterile Pharmaceuticals, §291.26, concerning Pharmacies Compounding Sterile Pharmaceuticals, and §291.27, concerning Pharmacy Residency Programs. The proposed new rules, amendments, and repeals, if adopted, provide a more organized Subchapter A of Chapter 291 regarding all classes of pharmacies.

New §291.2, if adopted, provides the definitions for the subchapter previously found in §291.16 which is proposed as a repealed rule published in this edition of the *Texas Register.* New §291.3, if adopted, contains the required notifications for pharmacies previously found in §§291.2, 291.3, 291.4, 291.7, 291.12, 291.15 and 291.21 which are proposed as repealed rules published in this edition of the *Texas Register.* New §291.24, if adopted, provides the standards for pharmacy residency programs previously found in §291.27 which is proposed as a repealed rule published in this edition of the *Texas Register.* New §291.27, if adopted, provides the confidentiality requirements for all classes of pharmacy previously located within the rules for each class of pharmacy and clarifies that pharmacy must have written polices and procedures to prohibit the unauthorized disclosure of confidential records. The amendments to §291.6, if adopted, will raise pharmacy license fees based on increased expense. The amendments to §291.8, if adopted, will implement Senate Bill 1188 passed by the 79th Texas Legislature which made changes to the Texas Pharmacy Act, allowing for the return of certain prescription drugs in sealed unopened tamper-evident individual packaging and either individually packaged or packaged in unit-dose packaging and will allow for the return of certain unused prescription drugs for penal institutions. The amendments to §291.10, if adopted, will clarify the board's authority to inspect balances in pharmacies. The amendments to §291.18, if adopted, correct punctuation. The amendments to §291.19, if adopted, clarify inspection procedures. The amendments to §291.22, if adopted, correct grammar. The amendments to §291.23, update the reference to the Texas Pharmacy Act. The §§291.13, 291.20, 291.25, and 291.26 are proposed as new rules in new Subchapter G of Chapter 291 and are published elsewhere in this edition of the *Texas Register.*

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the amendments are in effect, there will be fiscal implications for state government as a result of enforcing or administering the proposal as follows:

Revenue Increase

FY2008 = $321,750

FY2009 = $351,000

FY2010 = $351,000

FY2011 = $351,000

FY2012 = $351,000

There are no anticipated fiscal implications for local government.

Ms. Dodson has determined that, for each year of the first five year period the proposal will be in effect, the public benefit anticipated as a result of enforcing the proposal will be assuring that the Texas State Board of Pharmacy is adequately funded to carry out its mission. The effect on large, small or micro-businesses (pharmacies) required to comply with the proposal will be an increase of $117 for an initial registration and an increase of $117 for the renewal of a registration.

The economic cost to an individual will be the same as the economic cost to a business, if the individual chooses to pay the business registration fee.

Comments on the proposed new rules, amendments and repeals may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas, 78701, FAX (512) 305-8082. Comments must be received by 5:00 p.m., July 30, 2007.

22 TAC §§291.2 - 291.4, 291.7, 291.12, 291.13, 291.15, 291.16, 291.20, 291.21, 291.25 - 291.27

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the offices of the Texas State Board of Pharmacy or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by the repeal: Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.2. Change of Location and/or Name.

§291.3. Change of Managing Officers.

§291.4. Change of Ownership.

§291.7. Change of Pharmacist Employment.

§291.12. Fire or Other Disaster.

§291.13. Emergency Remote Pharmacy License.

§291.15. Notification of Theft or Loss of a Controlled Substance or a Dangerous Drug.

§291.16. Definitions.

§291.20. Remote Pharmacy Services.

§291.21. Notification to Consumers.

§291.25. Pharmacies Compounding Non-Sterile Pharmaceuticals.

§291.26. Pharmacies Compounding Sterile Pharmaceuticals.

§291.27. Pharmacy Residency Programs.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702221
Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 305-8028

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22 TAC §§291.2, 291.3, 291.6, 291.8, 291.10, 291.18, 291.19, 291.22 - 291.24, 291.27

The amendments and new rules are proposed under §§551.002, 554.051, and 562.1085 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act. The Board interprets §562.1085 as authorizing the agency to adopt rules to implement the provisions of the section.

The statutes affected by the amendments and new rules: Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.2. Definitions.

Any term not defined in this chapter shall have the definition set out in the Act, §551.003.

§291.3. Required Notifications.

(a) Change of Location and/or Name.

(1) When a pharmacy changes location and/or name, the following is applicable.

(A) A new completed pharmacy application containing the information outlined in §291.1 of this title (relating to Pharmacy License Application), must be filed with the board within 10 days of the change of location of the pharmacy.

(B) The previously issued license must be returned to the board office.

(C) An amended license reflecting the new location and/or name of the pharmacy will be issued by the board; and

(D) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for issuance of the amended license.

(2) Disasters, accidents, and emergencies which require the pharmacy to change location shall be immediately reported to the board.

(b) Change of Managing Officers.

(1) The owner of a pharmacy shall notify the board in writing within 10 days of a change of any managing officer of a partnership or corporation which owns a pharmacy. The written notification shall include the effective date of such change and the following information for all managing officers:

(A) name and title;

(B) home address and telephone number;

(C) date of birth; and

(D) social security number.

(2) For purposes of this subsection, managing officers are defined as the top four executive officers, including the corporate officer in charge of pharmacy operations, who are designated by the partnership or corporation to be jointly responsible for the legal operation of the pharmacy.

(c) Change of Ownership.

(1) When a pharmacy changes ownership, a new/completed pharmacy application must be filed with the board and the licensed issued to previous owner shall be returned to the board.

(2) The new application shall include the following information:

(A) the name and address of pharmacy;

(B) the type of ownership;

(C) the names, home addresses, dates of birth, phone numbers, and social security numbers of all owners; if a partnership or corporation, the name, title, home address, home phone number, date of birth, and social security number of all managing officers;

(D) the name and license number of the pharmacist-in-charge and of other pharmacists employed by the pharmacy;

(E) a copy of lease agreement or alternatively, a notarized statement signed by the lessee and lessor certifying the existence of a lease agreement, or if the location of the pharmacy is owned by the applicant, a notarized statement certifying such location ownership;

(F) a copy of the purchase contract or mutual agreement between the buyer and seller, or a notarized statement of intent to convey ownership signed by both the buyer and seller, stating the proposed date of ownership change;

(G) the signature of the pharmacist-in-charge;

(H) the notarized signature of the owner, or if the pharmacy is owned by a partnership or corporation, the notarized signature of an owner or managing officer;

(I) federal tax ID number;

(J) description of business services that will be offered;

(K) name and address of malpractice insurance carrier or statement that the business will be self-insured;

(L) the certificate of authority, if applicant is an out-of-state corporation;

(M) the articles of incorporation, if the applicant is a corporation;

(N) a current Texas Franchise Tax Certificate of Good Standing; and

(O) any other information requested on the application.

(3) Paragraph (4) of this subsection applies to all change of ownership applications for Class A (Community) pharmacies or Class C (Institutional) pharmacies owned by a management company with the following exceptions.

(A) Paragraph (4) of this subsection does not apply to a change of ownership application submitted by an entity which already owns a pharmacy licensed in Texas.

(B) Paragraph (4)(A) and (C) of this subsection do not apply to each individual owner or managing officer listed on a new pharmacy application if the individual possesses an active pharmacist license in Texas.

(4) If the pharmacy is to be licensed as a Class A (Community) Pharmacy or a Class C (Institutional) pharmacy owned by a management company, the applicant must submit copies of the following documents in addition to the information required in paragraph (2) of this subsection:

(A) the birth certificate, passport, or other document proving the date of birth of the owner, or, if the pharmacy is owned by a partnership or a closely held corporation:

(i) one of these documents for each managing officer; and

(ii) a list of all owners of the corporation;

(B) an approved credit application from a primary wholesaler or other documents showing credit worthiness as approved by the Board; and

(C) a current driver license or state issued photo ID card of each individual owner, or, if the pharmacy is owned by a partnership or a closely held corporation, a current driver license or state issued photo ID card for each managing officer.

(5) A fee as specified in §291.6 of this title will be charged for issuance of a new license.

(d) Change of Pharmacist Employment.

(1) Change of pharmacist employed in a pharmacy. When a change in pharmacist employment occurs, the pharmacist shall report such change in writing to the board within 10 days. The pharmacist-in-charge shall delete or enter the name of the pharmacist changing employment on the license of such pharmacy.

(2) Change of pharmacist-in-charge of a pharmacy.

(A) On the date of change of the pharmacist-in-charge of a Class A (community) or Class C (institutional) pharmacy, an inventory of the following shall be taken:

(i) all Schedule II controlled substances;

(ii) all dosage forms containing pentazocine (e.g., Talwin);

(iii) all dosage forms containing phentermine (e.g., Ionamin, Fastin, Adipex-P, etc.);

(iv) all dosage forms containing diazepam (e.g., Valium);

(v) all dosage forms containing phendimetrazine (e.g., Bontril, Plegine, Prelu-2, etc.);

(vi) all dosage forms containing codeine;

(vii) all dosage forms containing hydrocodone (e.g., Tussionex, Tussend, Vicodin, Hycomine, etc.);

(viii) all dosage forms containing alprazolam (e.g., Xanax);

(ix) all dosage forms containing triazolam (e.g., Halcion);

(x) all dosage forms containing butorphanol (e.g., Stadol);

(xi) all dosage forms containing nalbuphine (e.g., Nubain); and

(xii) all dosage forms containing carisoprodol (e.g., Soma).

(B) This inventory shall constitute, for the purpose of this section, the closing inventory of the departing pharmacist-in-charge and the beginning inventory of the incoming pharmacist-in-charge.

(C) If the departing and the incoming pharmacists-in-charge are unable to conduct the inventory together, a closing inventory shall be conducted by the departing pharmacist-in-charge and a new and separate beginning inventory shall be conducted by the incoming pharmacist-in-charge.

(D) The incoming pharmacist-in-charge shall be responsible for the following actions:

(i) deleting the name of the departing pharmacist-in-charge on the pharmacy license;

(ii) entering the name of the incoming pharmacist-in-charge on the pharmacy license;

(iii) notifying the board within 10 days in writing on a form provided by the board, that a change of pharmacist-in-charge has occurred. The notification shall include the following:

(I) the name and license number of the departing pharmacist-in-charge;

(II) the name and license number of the incoming pharmacist-in-charge;

(III) the date the incoming pharmacist-in-charge became the pharmacist-in-charge; and

(IV) a statement signed by the incoming pharmacist-in-charge attesting that:

(-a-) an inventory has been conducted by the departing and incoming pharmacists-in-charge; if the inventory was not taken by both pharmacists, the statement shall provide an explanation; and

(-b-) the incoming pharmacist-in-charge has read and understands the laws and rules relating to this class of pharmacy.

(e) Notification of Theft or Loss of a Controlled Substance or a Dangerous Drug.

(1) Controlled substances. For the purposes of the Act, §562.106, the theft or significant loss of any controlled substance by a pharmacy shall be reported in writing to the board immediately on discovery of such theft or loss. A pharmacy shall be in compliance with this subsection by submitting to the board a copy of the Drug Enforcement Administration (DEA) report of theft or loss of controlled substances, DEA Form 106, or by submitting a list of all controlled substances stolen or lost.

(2) Dangerous drugs. A pharmacy shall report in writing to the board immediately on discovery the theft or significant loss of any dangerous drug by submitting a list of the name and quantity of all dangerous drugs stolen or lost.

(f) Fire or Other Disaster. If a pharmacy experiences a fire or other disaster, the following requirements are applicable.

(1) Responsibilities of the pharmacist-in-charge.

(A) The pharmacist-in-charge shall be responsible for reporting the date of the fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of the injury, illness, and disease; such notification shall be immediately reported to the board, but in no event shall exceed 10 days from the date of the disaster.

(B) The pharmacist-in-charge or designated agent shall comply with the following procedures.

(i) If controlled substances, dangerous drugs, or Drug Enforcement Administration (DEA) order forms are lost or destroyed in the disaster, the pharmacy shall:

(I) notify the DEA, Department of Public Safety (DPS), and Texas State Board of Pharmacy (board) of the loss of the controlled substances or order forms. A pharmacy shall be in compliance with this section by submitting to each of these agencies a copy of the DEA's report of theft or loss of controlled substances, DEA Form-106, immediately on discovery of the loss; and

(II) notify the Texas State Board of Pharmacy in writing of the loss of the dangerous drugs by submitting a list of the dangerous drugs lost.

(ii) If the extent of the loss of controlled substances or dangerous drugs is not able to be determined, the pharmacy shall:

(I) take a new, complete inventory of all remaining drugs specified in §291.17(c) of this title (relating to Inventory Requirements);

(II) submit to DEA and DPS a statement attesting that the loss of controlled substances is indeterminable and that a new, complete inventory of all remaining controlled substances was conducted and state the date of such inventory; and

(III) submit to the board a statement attesting that the loss of controlled substances and dangerous drugs is indeterminable and that a new, complete inventory of the drugs specified in §291.17(c) of this title was conducted and state the date of such inventory.

(C) If the pharmacy changes to a new, permanent location, the pharmacist-in-charge shall comply with subsection (a) of this section.

(D) If the pharmacy moves to a temporary location, the pharmacist shall comply with subsection (a) of this section. If the pharmacy returns to the original location, the pharmacist-in-charge shall again comply with subsection (a) of this section.

(E) If the pharmacy discontinues business (ceases to operate as a pharmacy), the pharmacist-in-charge shall comply with §291.5 of this title (relating to Closed Pharmacies).

(F) The pharmacist-in-charge shall maintain copies of all inventories, reports, or notifications required by this section for a period of two years.

(2) Drug stock.

(A) Any drug which has been exposed to excessive heat, smoke, or other conditions which may have caused deterioration shall not be dispensed.

(B) Any potentially adulterated or damaged drug shall only be sold, transferred, or otherwise distributed pursuant to the provisions of the Texas Food Drug and Cosmetics Act (Chapter 431, Health and Safety Code) administered by the Bureau of Food and Drug Safety of the Texas Department of State Health Services.

(g) Notification to Consumers.

(1) Pharmacy.

(A) Every licensed pharmacy shall provide notification to consumers of the name, mailing address, Internet site address, and telephone number of the board for the purpose of directing complaints concerning the practice of pharmacy to the board. Such notification shall be provided as follows.

(i) If the pharmacy serves walk-in customers, the pharmacy shall either:

(I) post in a prominent place that is in clear public view where prescription drugs are dispensed a sign furnished by the board which notifies the consumer that complaints concerning the practice of pharmacy may be filed with the board and list the board's name, mailing address, Internet site address, telephone number of the board, and if applicable a toll-free telephone number for filing complaints; or

(II) provide with each dispensed prescription a written notification in a type size no smaller than ten-point Times Roman which states the following: "Complaints concerning the practice of pharmacy may be filed with the Texas State Board of Pharmacy at: (list the mailing address, Internet site address, telephone number of the board, and if applicable a toll-free telephone number for filing complaints)."

(ii) If the prescription drug order is delivered to patients at their residence or other designated location, the pharmacy shall provide with each dispensed prescription a written notification in type size no smaller than ten-point Times Roman which states the following: "Complaints concerning the practice of pharmacy may be filed with the

Texas State Board of Pharmacy at: (list the mailing address, Internet site address, telephone number of the board, and if applicable a toll-free telephone number for filing complaints)." If multiple prescriptions are delivered to the same location, only one such notice shall b required.

(iii) The provisions of this subsection do not apply to prescriptions for patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).

(B) A pharmacy that maintains a generally accessible site on the Internet that is located in Texas or sells or distributes drugs through this site to residents of this state shall post the following information on the pharmacy's initial home page and on the page where a sale of prescription drugs occurs.

(i) Information on the ownership of the pharmacy, to include at a minimum, the:

(I) owner's name or if the owner is a partnership or corporation, the partnership's or corporation's name and the name of the chief operating officer;

(II) owner's address;

(III) owner's telephone number; and

(IV) year the owner began operating pharmacies in the United States.

(ii) The Internet address and toll free telephone number that a consumer may use to:

(I) report medication/device problems to the pharmacy; and

(II) report business compliance problems.

(iii) Information about each pharmacy that dispenses prescriptions for this site, to include at a minimum, the:

(I) pharmacy's name, address, and telephone number;

(II) name of the pharmacist responsible for operation of the pharmacy;

(III) Texas pharmacy license number for the pharmacy and a link to the Internet site maintained by the Texas State Board of Pharmacy; and

(IV) the names of all other states in which the pharmacy is licensed, the license number in that state, and a link to the Internet site of the entity that regulates pharmacies in that state, if available.

(C) A pharmacy whose Internet site has been awarded a Verified Internet Pharmacy Practice Site (VIPPS) certification by the National Association of Boards of Pharmacy shall be in compliance with subparagraph (B) of this paragraph by displaying the VIPPS seal on the pharmacy internet site.

(2) Texas State Board of Pharmacy. On or before January 1, 2005, the board shall establish a pharmacy profile system as specified in §2054.2606, Government Code.

(A) The board shall make the pharmacy profiles available to the public on the agency's Internet site.

(B) A pharmacy profile shall contain at least the following information:

(i) name, address, and telephone number of the pharmacy;

(ii) pharmacy license number, licensure status, and expiration date of the license;

(iii) the class and type of the pharmacy;

(iv) ownership information for the pharmacy;

(v) names and license numbers of all pharmacists working at the pharmacy;

(vi) whether the pharmacy has had prior disciplinary action by the board;

(vii) whether the pharmacy's consumer service areas are accessible to disabled persons, as defined by law;

(viii) the type of language translating services, including translating services for persons with impairment of hearing, that the pharmacy provides for consumers; and

(ix) insurance information including whether the pharmacy participates in the state Medicaid program.

(C) The board shall gather this information on initial licensing and update the information in conjunction with the license renewal for the pharmacy.

§291.6. Pharmacy License Fees.

(a) Initial License Fee.

(1) The fee for an initial license shall be $443 [~~$329~~] for a two year registration and for processing the application and issuance of the pharmacy license as authorized by the Act §554.006.

(2) In addition, the following fees shall be collected:

(A) $15 [~~$12~~] surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act §564.051;

(B) - (C) (No change.)

(3) (No change.)

(b) (No change.)

(c) Renewal Fee.

(1) The fee for biennial renewal of a pharmacy license shall be $443 [~~$329~~] for processing the application and issuance of the pharmacy license as authorized by the Act §554.006;

(2) In addition, the following fees shall be collected:

(A) $15 [~~$12~~] surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act §564.051;

(B) - (C) (No change.)

(d) (No change.)

§291.8. Return of Prescription Drugs.

(a) (No change.)

(b) Return of prescription drugs from health care facilities.

(1) Purpose. The purpose of this subsection is to outline procedures for the return of unused drugs from a health care facility or a penal institution to a dispensing pharmacy as specified in the §562.1085 of the Occupations Code. Nothing in this section shall require a consultant pharmacist, health care facility, penal institution, or pharmacy to participate in the return of unused drugs.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(A) - (B) (No change.)

(C) Licensed health care professional--A person licensed by the Texas Medical Board, Texas Board of Nurse Examiners, or the Texas State Board of Pharmacy.

(D) Penal institution--A place designated by law for confinement of persons arrested for, charged with, or convicted of an offense. A penal institution includes a city, county or state jail or prison.

(3) Consultant pharmacist/health care facility licensed health care professional/penal institution responsibilities. A consultant pharmacist or licensed health care professional may return to a pharmacy certain unused drugs, other than a controlled substance as defined by Chapter 481, Health and Safety Code, purchased from the pharmacy.

(A) The unused drugs must:

(i) be approved by the federal Food and Drug Administration and be:

(I) sealed in [~~the manufacturer's original~~] unopened tamper-evident packaging and either individually packaged or packaged in unit-dose packaging;

(II) - (III) (No change.)

(IV) parenteral medications in sealed multiple-dose containers approved by the federal Food and Drug Administration from which doses have not been withdrawn.[~~; and~~]

(ii) not be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug seller or manufacturer; and[~~.~~]

(iii) have not been in the physical possession of the person for whom it was prescribed.

(B) (No change.)

(C) The consultant pharmacist/licensed health care professional shall be responsible for assuring an inventory of the drugs to be returned to a pharmacy is completed. The following information shall be included on this inventory:

(i) (No change.)

(ii) name and pharmacist license number of the consultant pharmacist or name and license number of the licensed health care professional;

(iii) - (vii) (No change.)

(viii) signature of consultant pharmacist.[~~;~~]

(D) The health care facility/penal institution shall send a copy of the inventory specified in subparagraph (C) of this paragraph to:

(i) - (ii) (No change.)

(4) Dispensing/Receiving pharmacy responsibilities. If a pharmacy accepts the return of unused drugs from a health care facility/penal institution, the following is applicable.

(A) - (C) (No change.)

(5) (No change.)

§291.10. Pharmacy Balance Registration/Inspection.

(a) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Pharmacy balance--An instrument for weighing including [~~ingredients used in the compounding of drugs in a pharmacy. The term pharmacy balance includes~~] balances and scales.

(b) Registration.

(1) A pharmacy shall annually or biennially register each pharmacy balance [~~which may be used in the compounding of drugs~~]. The fee for the annual registration shall be $12.50 per pharmacy balance. The fee for the biennial registration shall be $25.00 per pharmacy balance.

(2) (No change.)

(c) Inspection.

(1) (No change.)

(2) If a pharmacy balance fails the accuracy inspection, the following is applicable.

(A) The pharmacy balance may not be used [~~in the compounding of drugs~~] until it is repaired by an authorized repair person.

(B) (No change.)

§291.18. Time Limit for Filing a Complaint.

For the purposes of the Act, §556.055, the board determines that a "reasonable time" [~~:~~] to be no less than 10 days from the date of an inspection giving rise to a possible complaint; provided, however, in situations presenting imminent danger to the public health and safety, the board may obtain an injunction under the Act, §566.051, to restrain or enjoin a person from continuing to violate the Act or rules promulgated pursuant to the Act without waiting the 10-day period set out in this section.

§291.19. Administrative Actions as a Result of a Compliance Inspection.

As a result of a compliance inspection or compliance reinspection of a pharmacy wherein violations of the Texas Pharmacy Act, Controlled Substances Act, Dangerous Drug Act, Texas Food, Drug and Cosmetic Act, or rules adopted pursuant to such acts as observed:

(1) an agent [~~a compliance officer~~] of the board may issue a written report of areas of non-compliance that need improvement;

(2) an agent [~~a compliance officer~~] of the board may issue a written warning notice listing specific violations to which the licensee shall respond in writing to the board by the date stated on the warning notice, indicating that the violations listed in the warning notice have been corrected;

(3) an agent [~~a compliance officer~~] of the board may recommend the institution of disciplinary action against a licensee if such agent [~~compliance officer~~] determines that:

(A) - (B) (No change.)

(4) an agent [~~a compliance officer~~] of the board, upon determination that the violations observed are of a nature that pose an imminent peril to the public health, safety, or welfare, may recommend to the director of compliance, the institution of action by a district court in Travis County, Texas, to restrain or enjoin a licensee from continuing the violation, in addition to recommending the institution of disciplinary action against a licensee.

§291.22. Petition to Establish an Additional Class of Pharmacy.

(a) (No change.)

(b) Procedures for petitioning the board to establish an additional class of pharmacy. A person who wishes the board to consider establishing an additional class of pharmacy shall submit to the board a petition that [~~for which~~] contains at least the following information:

(1) - (2) (No change.)

(c) (No change.)

§291.23. Pilot or Demonstration Research Projects for Innovative Applications in the Practice of Pharmacy.

(a) Purpose. The purpose of this section is to specify the procedures to be followed in applying for approval of a pilot or demonstration research project for innovative applications in the practice of pharmacy as authorized by §554.011 of the Texas Pharmacy Act (Chapters 551- 566 and 568 - 569, Texas Occupations Code). In reviewing projects, the board will only consider projects that expand pharmaceutical care services which contribute to positive patient outcomes. The board will not consider any project intended only to provide a competitive advantage.

(b) - (e) (No change.)

§291.24. Pharmacy Residency Programs.

For the purposes of Subchapter T, Chapter 61, Education Code, the standards for pharmacy residency programs shall be the standards required by the American Society of Health-System Pharmacists' Commission on Credentialing. The pharmacy residency programs approved by the Board shall be published periodically in the minutes of the Board.

§291.27. Confidentiality.

(a) A pharmacist shall provide adequate security of prescription drug orders, medication orders, and patient medication records to prevent indiscriminate or unauthorized access to confidential health information. If prescription drug orders, requests for refill authorization, or other confidential health information are not transmitted directly between a pharmacy and a physician but are transmitted through a data communication device, confidential health information may not be accessed or maintained by the operator of the data communication device unless specifically authorized to obtain the confidential information by this section.

(b) Confidential records are privileged and may be released only to:

(1) the patient or the patient's agent;

(2) a practitioner or another pharmacist if, in the pharmacist's professional judgement, the release is necessary to protect the patient's health and well being;

(3) the board or to a person or another state or federal agency authorized by law to receive the confidential record;

(4) a law enforcement agency engaged in investigation of a suspected violation of Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.);

(5) a person employed by a state agency that licenses a practitioner, if the person is performing the person's official duties; or

(6) an insurance carrier or other third party payor authorized by a patient to receive such information.

(c) A pharmacy shall provide written polices and procedures to prohibit the unauthorized disclosure of confidential records.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702219
Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 305-8028

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SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

22 TAC §§291.31 - 291.34

The Texas State Board of Pharmacy proposes amendments to §291.31 concerning Definitions, §291.32 concerning Personnel, §291.33 concerning Operational Standards, and §291.34 concerning Records. The Texas State Board of Pharmacy proposes the repeal of §291.37 concerning Centralized Prescription Dispensing and §291.38 concerning Central Prescription Drug or Medication Order Processing. The proposed amendments to §291.31, if adopted, clarify the definition for hot water, update and clarify the definitions for pharmacy technicians and pharmacy technician trainees, and clarify the definition for prescription drug. The proposed amendments to §291.32, if adopted, clarify that a pharmacist must check the data entry of a prescription, at the time of data entry when the prescription is placed "on hold" and update the rules to include pharmacy technician trainees. The proposed amendments to §291.33, if adopted, correct references to other rules in the chapter, correct the alternative labeling requirements for customized patient medication packages to conform with changes made to the alternative labeling requirements for dispensing containers, allow for the reuse of certain types of prescription containers if the patient or patient's agent has difficulty reading or understanding the prescription label, and incorporate recommendations made by the Task Force on Security in Community (Class A) Pharmacies. The proposed amendments to §291.34, if adopted, require pharmacies to provide the board or its representative with records in electronic format, if the records are maintained in an electronic format, and updates and corrects references. The §291.37 and §291.38 are proposed as new rules in new Subchapter G of Chapter 291 and are published elsewhere in this edition of the *Texas Register*.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the proposed rule amendments are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Ms. Dodson has determined that, for each year of the first five-year period §291.31 will be in effect, the public benefit anticipated as a result of enforcing the proposed rule amendments will be to ensure that pharmacies have access to hot water as defined by the rule; for each year of the first five-year period §291.32 will be in effect, the public benefit anticipated as a result of enforcing the rules will be to ensure that prescriptions placed "on hold" are checked by a pharmacist; for each year of the first five-year period §291.33 will be in effect, the public benefit anticipated as a result of enforcing the rule will be to ensure the security of Class A pharmacies and to prohibit the diversion of prescription drugs from Class A pharmacies, and will be to allow pharmacies to reuse certain types of prescription containers for patients that have difficulty reading prescription labels; for each

year of the first five-year period §291.34 will be in effect, the public benefit anticipated as a result of enforcing the rule will be to ensure that pharmacies provide records to the Board in the requested format. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with §§291.31, 291.32, 291.34. There may be pharmacies that would be required to obtain security systems that comply with §291.33. However, it is difficult to project the exact costs due to variations in pharmacy size, settings, and types of systems available.

A public hearing to receive comments on the proposed §291.33 with regard to the security requirements will be held at 9:00 a.m. on Tuesday, August 7, 2007, at the Health Professions Council Board Room, 333 Guadalupe Street, Tower II, Room 2-225, Austin, Texas 78701. Persons planning to present comments to the Board are asked to provide a written copy of their comments prior to the hearing or bring 20 copies to the hearing. Written comments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, 333 Guadalupe Street, Suite 3-600, Austin, Texas, 78701, FAX: (512) 305-8082, E-mail: allison.benz@tsbp.state.tx.us. Comments must be received by 5:00 p.m., July 30, 2007.

The amendments are proposed under §551.002, and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by the amendments: Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.31. Definitions.

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) - (22) (No change.)

(23) Hot water--The temperature of water from the pharmacy's sink maintained at 120 to 140 degrees F (49 to 60 C).

(24) [~~(23)~~] Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

(25) [~~(24)~~] Medication order--A written order from a practitioner or a verbal order from a practitioner or his authorized agent for administration of a drug or device.

(26) [~~(25)~~] New prescription drug order--A prescription drug order that:

(A) has not been dispensed to the patient in the same strength and dosage form by this pharmacy within the last year;

(B) is transferred from another pharmacy; and/or

(C) is a discharge prescription drug order. (Note: furlough prescription drug orders are not considered new prescription drug orders.)

(27) [~~(26)~~] Original prescription--The:

(A) original written prescription drug order; or

(B) original verbal or electronic prescription drug order reduced to writing either manually or electronically by the pharmacist.

(28) [~~(27)~~] Part-time pharmacist--A pharmacist who works less than full-time.

(29) [~~(28)~~] Patient counseling--Communication by the pharmacist of information to the patient or patient's agent in order to improve therapy by ensuring proper use of drugs and devices.

(30) [~~(29)~~] Pharmaceutical care--The provision of drug therapy and other pharmaceutical services intended to assist in the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

(31) [~~(30)~~] Pharmacist-in-charge--The pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(32) [~~(31)~~] Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist. [~~Pharmacy technician includes registered pharmacy technicians and pharmacy technician trainees.~~]

(33) [~~(32)~~] Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program. [~~A person who is not registered as a pharmacy technician by the board and is either:~~]

[~~(A) participating in a pharmacy's technician training program; or~~]

[~~(B) currently enrolled in a:~~]

[~~(i)~~ ~~pharmacy technician training program accredited by the American Society of Health-System Pharmacists; or~~]

[~~(ii)~~ ~~health science technology education program in a Texas high school that is accredited by the Texas Education Agency.~~]

(34) [~~(33)~~] Physician assistant--A physician assistant recognized by the Texas State Board of Medical Examiners as having the specialized education and training required under Subtitle B, Chapter 157, Occupations Code, and issued an identification number by the Texas State Board of Medical Examiners.

(35) [~~(34)~~] Practitioner--

(A) a person licensed or registered to prescribe, distribute, administer, or dispense a prescription drug or device in the course of professional practice in this state, including a physician, dentist, podiatrist, or veterinarian but excluding a person licensed under this subtitle;

(B) a person licensed by another state, Canada, or the United Mexican States in a health field in which, under the law of this state, a license holder in this state may legally prescribe a dangerous drug;

(C) a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration registration number and who may legally prescribe a Schedule II, III, IV, or V controlled substance, as specified under Chapter 481, Health and Safety Code, in that other state; or

(D) an advanced practice nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders under §§157.0511, 157.052, 157.053, 157.054, 157.0541, or 157.0542, Occupations Code.

(36) [~~(35)~~] Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container into a prescription container for dispensing by a pharmacist to the ultimate consumer.

(37) Prescription drug--

(A) a substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;

(B) a drug or device that under federal law is required, before being dispensed or delivered, to be labeled with the statement:

(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or

(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(C) a drug or device that is required by federal or state statute or regulation to be dispensed on prescription or that is restricted to use by a practitioner only.

(38) [~~(36)~~] Prescription drug order--

(A) a written order from a practitioner or a verbal order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) a written order or a verbal order pursuant to Subtitle B, Chapter 157, Occupations Code.

(39) [~~(37)~~] Prospective drug use review--A review of the patient's drug therapy and prescription drug order or medication order prior to dispensing or distributing the drug.

(40) [~~(38)~~] State--One of the 50 United States of America, a U.S. territory, or the District of Columbia.

(41) [~~(39)~~] Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.

(42) [~~(40)~~] Written protocol--A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas State Board of Medical Examiners under the Texas Medical Practice Act.

§291.32. Personnel.

(a) Pharmacist-in-charge.

(1) General.

(A) Each Class A pharmacy shall have one pharmacist-in-charge who is employed on a full-time basis, who may be the pharmacist-in-charge for only one such pharmacy; provided, however, such pharmacist-in-charge may be the pharmacist-in-charge of:

(i) more than one Class A pharmacy, if the additional Class A pharmacies are not open to provide pharmacy services simultaneously; or

(ii) up to two Class A pharmacies open simultaneously if the pharmacist-in-charge works at least 10 hours per week in each pharmacy.

(B) The pharmacist-in-charge shall comply with the provisions of §291.17 of this title (relating to Inventory Requirements).

(2) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-charge may advise the owner on administrative or operational concerns. The pharmacist-in-charge shall have responsibility for, at a minimum, the following:

(A) education and training of pharmacy technicians and pharmacy technician trainees;

(B) supervising a system to assure appropriate procurement of prescription drugs and devices and other products dispensed from the Class A pharmacy;

(C) disposal and distribution of drugs from the Class A pharmacy;

(D) storage of all materials, including drugs, chemicals, and biologicals;

(E) maintaining records of all transactions of the Class A pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials required by applicable state and federal laws and sections;

(F) supervising a system to assure maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs;

(G) adherence to policies and procedures regarding the maintenance of records in a data processing system such that the data processing system is in compliance with Class A (community) pharmacy requirements;

(H) legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or sections governing the practice of pharmacy; and

(I) [~~effective September 1, 2000,~~] if the pharmacy uses an automated pharmacy dispensing system, shall be responsible for the following:

(i) consulting with the owner concerning and adherence to the policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(ii) inspecting medications in the automated pharmacy dispensing system, at least monthly, for expiration date, misbranding, physical integrity, security, and accountability;

(iii) assigning, discontinuing, or changing personnel access to the automated pharmacy dispensing system;

(iv) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed healthcare professionals performing any services in connection with an automated pharmacy dispensing system have been properly trained on the use of the system and can demonstrate comprehensive knowledge of the written policies and procedures for operation of the system; and

(v) ensuring that the automated pharmacy dispensing system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

(b) (No change.)

(c) Pharmacists.

(1) General.

(A) The pharmacist-in-charge shall be assisted by sufficient number of additional licensed pharmacists as may be required to operate the Class A pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

(B) All pharmacists shall assist the pharmacist-in-charge in meeting his or her responsibilities in ordering, dispensing, and accounting for prescription drugs.

(C) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for designating and delegating duties, other than those listed in paragraph (2) of this subsection, to pharmacy technicians and pharmacy technician trainees. Each pharmacist:

(i) shall verify the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees; and

(ii) shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

(D) Pharmacists shall directly supervise pharmacy technicians and pharmacy technician trainees who are entering prescription data into the pharmacy's data processing system by one of the following methods.

(i) Physically present supervision. A pharmacist shall be physically present to directly supervise a pharmacy technician or pharmacy technician trainee who is entering prescription data into the data processing system. Each prescription entered into the data processing system shall be verified at the time of data entry. If the pharmacist is not physically present due to a temporary absence as specified in §291.33(b)(4) of this title (relating to Operational Standards), on return the pharmacist must:

(I) conduct a drug regimen review for the prescriptions data entered during this time period as specified in §291.33(c)(2) of this title; and

(II) verify that prescription data entered during this time period was entered accurately [~~prior to delivery of the prescription to the patient or patient's agent~~].

(ii) Electronic supervision. A pharmacist may electronically supervise a pharmacy technician or pharmacy technician trainee who is entering prescription data into the data processing system provided the pharmacist:

(I) is on-site, in the pharmacy where the technician/trainee is located;

(II) has immediate access to any original document containing prescription information or other information related to the dispensing of the prescription. Such access may be through imaging technology provided the pharmacist has the ability to review the original, hardcopy documents if needed for clarification; and

(III) verifies the accuracy of the data entered information prior to the release of the information to the system for storage and/or generation of the prescription label.

(E) All pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(F) A dispensing pharmacist shall ensure that the drug is dispensed and delivered safely, and accurately as prescribed. In addition, if multiple pharmacists participate in the dispensing process, each pharmacist shall ensure the safety and accuracy of the portion of the process the pharmacist is performing. The dispensing process shall include, but not be limited to, drug regimen review and verification of accurate prescription data entry, including data entry of prescriptions placed on hold, packaging, preparation, compounding and labeling and performance of the final check of the dispensed prescription.

(2) Duties. Duties which may only be performed by a pharmacist are as follows:

(A) receiving oral prescription drug orders and reducing these orders to writing, either manually or electronically;

(B) interpreting prescription drug orders;

(C) selection of drug products;

(D) performing the final check of the dispensed prescription before delivery to the patient to ensure that the prescription has been dispensed accurately as prescribed;

(E) communicating to the patient or patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgement, the pharmacist deems significant, as specified in §291.33(c) of this title;

(F) communicating to the patient or the patient's agent on his or her request information concerning any prescription drugs dispensed to the patient by the pharmacy;

(G) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(H) interpreting patient medication records and performing drug regimen reviews; and

(I) performing a specific act of drug therapy management for a patient delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with the Medical Practice Act.

(3) Special requirements for compounding.

(A) Non-Sterile Preparations. [~~Pharmaceuticals.~~] All pharmacists engaged in compounding non-sterile preparations [~~pharmaceuticals~~] shall meet the training requirements specified in §291.131 [~~§291.25~~] of this title (relating to Pharmacies Compounding Non-sterile Preparations [~~Pharmaceuticals~~]).

(B) Sterile Preparations. [~~Pharmaceuticals.~~] All pharmacists engaged in compounding sterile preparations [~~pharmaceuticals~~] shall meet the training requirements specified in §291.133 [~~§291.26~~] of this title (relating to Pharmacies Compounding Sterile Preparations [~~Pharmaceuticals~~]).

(d) Pharmacy Technicians and Pharmacy Technician Trainees.

(1) General.

(A) All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Special requirements for compounding.

(i) Non-Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(ii) Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

~~[(A) On June 1, 2004, all persons employed as pharmacy technicians shall be either registered pharmacy technicians or pharmacy technician trainees as follows.]~~

~~*[(i)* All persons who have passed the required pharmacy technician certification examination shall be registered with the board under the provisions of this section.]~~

~~*[(ii)* All persons who have not taken and passed the required pharmacy certification examination may be designated pharmacy technician trainees, if qualified under the provisions of §297.5 of this title (relating to Pharmacy Technician Trainees).]~~

~~[(B) Between January 1, 2004, and May 31, 2004, all persons employed as pharmacy technicians who are qualified for registration by the board shall register according to the schedule designated by the board. Between January 1, 2004 and May 31, 2004, persons who are awaiting their scheduled time for registration and persons who have applied for registration, but the registration has not been completed shall comply with the rules in effect prior to January 1, 2004, relating to requirements and duties for certified or exempt pharmacy technicians.]~~

~~[(C) All pharmacy technicians shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician Training).]~~

~~[(D) Special requirements for compounding.]~~

~~*[(i)* Non-Sterile Pharmaceuticals. All pharmacy technicians engaged in compounding non-sterile pharmaceuticals shall meet the training requirements specified in §291.25 of this title (relating to Pharmacies Compounding Non-Sterile Pharmaceuticals).]~~

~~*[(ii)* Sterile Pharmaceuticals. Pharmacy technicians may compound sterile pharmaceuticals pursuant to medication orders provided the pharmacy technicians:]~~

~~*[(I)* have completed the training specified in §291.26 of this title (relating to Pharmacies Compounding Sterile Pharmaceuticals); and]~~

~~*[(II)* are supervised by a pharmacist who has completed the training specified in §291.26 of this title, conducts in-process and final checks, and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not required on the label if it is maintained in a permanent record of the pharmacy).]~~

(2) Duties.

(A) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in subsection (c)(2) of this section.

(B) A pharmacist may delegate to pharmacy technicians and pharmacy technician trainees any nonjudgmental technical duty associated with the preparation and distribution of prescription drugs provided:

(i) a pharmacist verifies the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees;

(ii) pharmacy technicians and pharmacy technician trainees are under the direct supervision of and responsible to a pharmacist; and

(iii) only pharmacy technicians and pharmacy technician trainees who have been properly trained on the use of an automated pharmacy dispensing system and can demonstrate comprehensive knowledge of the written policies and procedures for the operation of the system may be allowed access to the system; and

(C) Pharmacy technicians and pharmacy technician trainees may perform only nonjudgmental technical duties associated with the preparation and distribution of prescription drugs, as follows: ~~[including but not limited to the following:]~~

(i) initiating and receiving refill authorization requests;

(ii) entering prescription data into a data processing system;

(iii) taking a stock bottle from the shelf for a prescription;

(iv) preparing and packaging prescription drug orders (i.e., counting tablets/capsules, measuring liquids and placing them in the prescription container);

(v) affixing prescription labels and auxiliary labels to the prescription container; ~~[provided the pharmacy technician:]~~

~~*[(I)* has completed the education and training requirements outlined in §297.6 of this title; and]~~

~~*[(II)* is registered as a pharmacy technician within the provisions of §297.3 of this title (relating to Registration Requirements)]~~

(vi) reconstituting medications;

(vii) prepackaging and labeling prepackaged drugs;

(viii) loading bulk unlabeled drugs into an automated dispensing system provided a pharmacist verifies that the system is properly loaded prior to use;

(ix) compounding non-sterile and sterile prescription drug orders; and

(x) bulk compounding.

(3) Ratio of pharmacist to pharmacy technicians and pharmacy technician trainees.

(A) Except as provided in subparagraph (B) of this paragraph, the ratio of pharmacists to pharmacy technicians and pharmacy technician trainees may be 1:3, provided at least one of the three is a pharmacy technician. The ratio of pharmacists to pharmacy technician trainees may not exceed 1:2.

(B) As specified in §568.006 of the Act, a pharmacy that primarily compounds non-sterile pharmaceuticals may have a ratio of pharmacists to pharmacy technicians/pharmacy technician trainees of 1:5 provided:

(i) the pharmacy:

(I) dispenses no more than 20 different prescription drugs; and

(II) does not produce sterile preparations including intravenous or intramuscular drugs on-site; and

(ii) the following conditions are met:

(I) at least four are pharmacy technicians and not pharmacy technician trainees; and

(II) The pharmacy has written policies and procedures regarding the supervision of pharmacy technicians and pharmacy technician trainees, including requirements that the pharmacy technicians and pharmacy technician trainees included in a 1:5 ratio may be involved only in one process at a time. For example, a technician/trainee who is compounding non-sterile preparations may not also call physicians for authorization of refills.

[(A) Except as provided in subparagraphs (B) and (C) of this paragraph, the ratio of pharmacists to pharmacy technicians may not exceed 1:2.]

[(B) The ratio of pharmacists to pharmacy technicians may be 1:3, provided at least one of the three pharmacy technicians is a registered pharmacy technician.]

[(C) As specified in §568.006 of the Act, a pharmacy that primarily compounds non-sterile pharmaceuticals may have a ratio of pharmacists to pharmacy technicians of 1:5 provided:]

[(i) the pharmacy:]

[(I) dispenses no more than 20 different prescription drugs; and]

[(II) does not produce sterile pharmaceuticals including intravenous or intramuscular drugs on-site; and]

[(ii) the following conditions are met:]

[(I) at least four of the pharmacy technicians are registered pharmacy technicians; and]

[(II) The pharmacy has written policies and procedures regarding the supervision of pharmacy technicians, including requirements that the registered pharmacy technicians included in a 1:5 ratio may be involved only in one process at a time. For example, a technician who is compounding non-sterile pharmaceuticals may not also call physicians for authorization of refills.]

(e) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows.

(1) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that [which] bears the person's name and identifies him or her as a [pharmacy technician trainee, a registered] pharmacy technician, or a certified pharmacy technician, if the technician maintains current certification with the Pharmacy Technician Certification Board or any other entity providing an examination approved by the board. [Board.]

(2) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

(3) [(2)] Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that [which] bears the person's name and identifies him or her as a pharmacist intern.

(4) [(3)] Pharmacists. All pharmacists shall wear an identification tag or badge that [which] bears the person's name and identifies him or her as a pharmacist.

§291.33. Operational Standards.

(a) Licensing requirements.

(1) A Class A pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(2) A Class A pharmacy which changes ownership shall notify the board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications). [§291.4 of this title (relating to Change of Ownership).]

(3) A Class A pharmacy which changes location and/or name shall notify the board within ten days of the change and file for an amended license as specified in §291.3 of this title (relating to Required Notifications). [§291.2 of this title (relating to Change of Location and/or Name).]

(4) A Class A pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures in §291.3 of this title (relating to Required Notifications [Change of Managing Officers]).

(5) - (8) (No change.)

(9) A Class A (community) pharmacy engaged in the compounding of non-sterile pharmaceuticals shall comply with the provisions of §291.131 [§291.25] of this title (relating to Pharmacies Compounding Non-sterile Preparations [Pharmaceuticals]).

(10) A Class A (community) pharmacy engaged in the compounding of sterile pharmaceuticals shall comply with the provisions of §291.133 [§291.26] of this title (relating to Pharmacies Compounding Sterile Preparations [Pharmaceuticals]).

(11) A Class A (Community) pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 [§291.20] of this title (relating to Remote Pharmacy Services).

(12) Class A (Community) pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing). [§291.37 of this title (relating to Centralized Prescription Dispensing) and/or §291.38 of this title (relating to Centralized Prescription Drug or Medication Order Processing).]

(b) Environment.

(1) General requirements.

(A) The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be clean and in good operating condition.

(B) A Class A pharmacy shall have a sink with hot and cold running water within the pharmacy, exclusive of restroom facilities, available to all pharmacy personnel and maintained in a sanitary condition.

(C) A Class A pharmacy which serves the general public shall contain an area which is suitable for confidential patient counseling.

(i) Such counseling area shall:

(I) be easily accessible to both patient and pharmacists and not allow patient access to prescription drugs;

(II) be designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

(ii) In determining whether the area is suitable for confidential patient counseling and designed to maintain the confidentiality and privacy of the pharmacist/patient communication, the board may consider factors such as the following:

(I) the proximity of the counseling area to the check-out or cash register area;

(II) the volume of pedestrian traffic in and around the counseling area;

(III) the presence of walls or other barriers between the counseling area and other areas of the pharmacy; and

(IV) any evidence of confidential information being overheard by persons other than the patient or patient's agent or the pharmacist or agents of the pharmacist.

(D) The pharmacy shall be properly lighted and ventilated.

(E) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs; the temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

(F) Animals, including birds and reptiles, shall not be kept within the pharmacy and in immediately adjacent areas under the control of the pharmacy. This provision does not apply to fish in aquariums, guide dogs accompanying disabled persons, or animals for sale to the general public in a separate area that is inspected by local health jurisdictions.

(2) Security.

(A) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of prescription drugs, and records for such drugs.

(B) Any area of a pharmacy that contains prescription drugs shall be locked by key, combination or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site except as provided in subparagraphs (C) and (D) of this paragraph and paragraph (3) of this subsection. The following is applicable:

(i) Any area of a pharmacy that contains prescription drugs constructed after September 1, 2008, shall be enclosed by walls, partitions or other means of floor-to-ceiling enclosure. Pharmacies licensed prior to September 1, 2008, shall be exempt from this provision unless the pharmacy changes its address.

(ii) Effective, September 1, 2008, the pharmacy's key, combination or other mechanical or electronic means of locking the pharmacy may not be duplicated without the authorization of the pharmacist-in-charge or owner.

(iii) Effective, September 1, 2008, at a minimum, the pharmacy must have a basic alarm system and an electronic monitoring system to track individuals entering the area of a pharmacy that contains prescription drugs.

(C) Prior to authorizing individuals to enter the pharmacy, the pharmacist-in-charge may designate persons who may enter the pharmacy to perform functions documented by the pharmacist-in-charge including access to the pharmacy by other pharmacists, pharmacy personnel and other individuals. The pharmacy must maintain written documentation of authorized individuals other than pharmacy personnel who accessed the pharmacy when a pharmacist is not on-site.

(D) Only persons designated in writing by the pharmacist-in-charge may unlock the area of a pharmacy that contains prescription drugs except in emergency situations. An additional key to the area of a pharmacy that contains prescription drugs may be maintained in a secure location outside the area of a pharmacy that contains prescription drugs for use during an emergency or as designated by the pharmacist-in-charge for entry by another pharmacist.

(E) Written policies and procedures for the pharmacy's security shall be developed and implemented by the pharmacist-in-charge and/or the owner of the pharmacy. Such polices and procedures may include quarterly audits of controlled substances commonly abused or diverted, perpetual inventories, and monthly reports from the pharmacy's wholesaler(s) of controlled substances purchased by the pharmacy.

[(B) The prescription department shall be locked by key or combination so as to prevent access when a pharmacist is not on-site. However, the pharmacist-in-charge may designate persons who may enter the pharmacy to perform functions designated by the pharmacist-in-charge (e.g., janitorial services).]

(3) Temporary absence of pharmacist.

(A) On-site supervision by pharmacist.

(i) If a pharmacy is staffed by only one pharmacist, the pharmacist may leave the prescription department for breaks and meal periods without closing the prescription department and removing pharmacy technicians, pharmacy technician trainees, and other pharmacy personnel from the prescription department provided the following conditions are met:

(I) at least one pharmacy technician remains in the prescription department;

(II) the pharmacist remains on-site at the licensed location of the pharmacy and is immediately available;

(III) the absence does not exceed 30 minutes at a time and a total of one hour in a 12 hour period;

(IV) the pharmacist reasonably believes that the security of the prescription department will be maintained in his or her absence. If in the professional judgment of the pharmacist, the pharmacist determines that the prescription department should close during his or her absence, then the pharmacist shall close the prescription department and remove the pharmacy technicians, pharmacy technician trainees, or other pharmacy personnel from the prescription department during his or her absence; and

(V) a notice is posted which includes the following information:

(-a-) the fact that the pharmacist is on a break and the time the pharmacist will return; and

(-b-) the fact that pharmacy technicians may begin the processing of prescription drug orders or refills brought in during the pharmacist's absence, but the prescription or refill may not be delivered to the patient or the patient's agent until the pharmacist verifies the accuracy of the prescription.

(ii) During the time a pharmacist is absent from the prescription department, only pharmacy technicians who have completed the pharmacy's training program may perform the following duties, provided a pharmacist verifies the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent:

(I) initiating and receiving refill authorization requests;

(II) entering prescription data into a data processing system;

(III) taking a stock bottle from the shelf for a prescription;

(IV) preparing and packaging prescription drug orders (i.e., counting tablets/capsules, measuring liquids and placing them in the prescription container);

(V) affixing prescription labels and auxiliary labels to the prescription container provided the pharmacy technician:

(-a-) has completed the training requirements outlined in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training); and

(-b-) is registered as a pharmacy technician within the provisions of §297.3 of this title (relating to Registration Requirements); and

(VI) prepackaging and labeling prepackaged drugs.

(iii) Upon return to the prescription department, the pharmacist shall:

(I) conduct a drug regimen review as specified in subsection (c)(2) of this section; and

(II) verify the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent.

(iv) An agent of the pharmacist may deliver a previously verified prescription to the patient or his or her agent provided a record of the delivery is maintained containing the following information:

(I) date of the delivery;

(II) unique identification number of the prescription drug order;

(III) patient's name;

(IV) patient's phone number or the phone number of the person picking up the prescription; and

(V) signature of the person picking up the prescription.

(v) Any prescription delivered to a patient when a pharmacist is not in the prescription department must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.

(vi) During the times a pharmacist is absent from the prescription department a pharmacist intern shall be considered a registered pharmacy technician and may perform only the duties of a registered pharmacy technician.

(vii) In pharmacies with two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the prescription department is not left without a pharmacist on duty.

(B) Pharmacist is off-site.

(i) In a prescription department staffed by only one pharmacist during a shift, an agent of the pharmacist may deliver a previously verified prescription to a patient or patient's agent during short periods of time when a pharmacist is off-site, provided the following conditions are met:

(I) no more than a total of three pharmacy technicians or pharmacy technician trainees may remain in the pharmacy; however, at least one of the individuals must be a pharmacy technician;

(II) short periods of time may not exceed two consecutive hours in a 24 hour period and on no more than two occasions in a calendar month;

(III) the pharmacist reasonably believes the security of the pharmacy will be maintained in his or her absence. If, in the professional judgment of the pharmacist, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy during his or her absence;

(IV) a notice is posted which includes the following information:

(-a-) the fact that the pharmacist is off-site and not present in the pharmacy;

(-b-) the fact that no new prescriptions may be prepared at the pharmacy but previously verified prescriptions may be delivered to the patient or the patient's agent; and

(-c-) the date/time when the pharmacist will return; and

(V) the pharmacy must maintain written documentation of the absences of the pharmacist(s).

(ii) During the time, a pharmacist is absent from the pharmacy and is off-site, a record of prescriptions delivered must be maintained and contain the following information:

(I) date of the delivery;

(II) unique identification number of the prescription drug order;

(III) patient's name;

(IV) patient's phone number or the phone number of the person picking up the prescription;

(V) signature of the person picking up the prescription; and

(VI) dates and times that prescription drug orders were delivered to patients or patients' agents in the absence of the pharmacist;

(iii) Any prescription delivered to a patient when a pharmacist is not on-site at the pharmacy must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.

(iv) In pharmacies with two or more pharmacists working during a shift, the pharmacists shall stagger their schedules so that the pharmacy is not left without a pharmacist on duty.

~~[(A) If a pharmacy is staffed by a single pharmacist, the pharmacist may leave the prescription department for breaks and meal periods without closing the prescription department and removing pharmacy technicians and other pharmacy personnel from the prescription department provided the following conditions are met:]~~

~~*[(i)* at least one registered pharmacy technician remains in the prescription department;]~~

~~*[(ii)* the pharmacist remains on-site at the licensed location of the pharmacy and available for an emergency;]~~

~~*[(iii)* the absence does not exceed 30 minutes at a time and a total of one hour in a 12 hour period;]~~

~~*[(iv)* the pharmacist reasonably believes that the security of the prescription department will be maintained in his or her absence. If in the professional judgment of the pharmacist, the pharmacist determines that the prescription department should close during his or her absence, then the pharmacist shall close the prescription department and remove the pharmacy technicians or other pharmacy personnel from the prescription department during his or her absence; and]~~

~~*[(v)* a notice is posted which includes the following information:]~~

~~*[(I)* the fact that pharmacist is on a break and the time the pharmacist will return; and]~~

[*(II)* the fact that pharmacy technicians may begin the processing of prescription drug orders or refills brought in during the pharmacist absence but the prescription or refill may not be delivered to the patient or the patient's agent until the pharmacist returns and verifies the accuracy of the prescription.]

[(B) During the time a pharmacist is absent from the prescription department, only pharmacy technicians who have completed the pharmacy's training program may perform the following duties, provided a pharmacist verifies the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent:]

[*(i)* initiating and receiving refill authorization requests;]

[*(ii)* entering prescription data into a data processing system;]

[*(iii)* taking a stock bottle from the shelf for a prescription;]

[*(iv)* preparing and packaging prescription drug orders (i.e., counting tablets/capsules, measuring liquids and placing them in the prescription container);]

[*(v)* affixing prescription labels and auxiliary labels to the prescription container provided the pharmacy technician:]

[*(I)* has completed the training requirements outlined in §297.6 of this title (relating to Pharmacy Technician Training); and]

[*(II)* is registered as a pharmacy technician within the provisions of §297.3 of this title (relating to Registration Requirements); and]

[*(vi)* prepackaging and labeling prepackaged drugs.]

[(C) Upon return to the prescription department, the pharmacist shall:]

[*(i)* conduct a drug regimen review as specified in subsection (c)(2) of this section; and]

[*(ii)* verify the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent.]

[(D) An agent of the pharmacist may deliver a prescription drug order to the patient or his or her agent provided a record of the delivery is maintained containing the following information:]

[*(i)* date of the delivery;]

[*(ii)* unique identification number of the prescription drug order;]

[*(iii)* patient's name;]

[*(iv)* patient's phone number or the phone number of the person picking up the prescription; and]

[*(v)* signature of the person picking up the prescription.]

[(E) Any prescription delivered to a patient when a pharmacist is not in the prescription department must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.]

[(F) During the times a pharmacist is absent from the prescription department a pharmacist intern shall be considered a registered pharmacy technician and may perform only the duties of a registered pharmacy technician.]

[(G) In pharmacies with two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the prescription department is not left without a pharmacist on duty.]

(c) Prescription dispensing and delivery.

(1) Patient counseling and provision of drug information.

(A) To optimize drug therapy, a pharmacist shall communicate to the patient or the patient's agent, information about the prescription drug or device which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, such as the following:

(i) the name and description of the drug or device;

(ii) dosage form, dosage, route of administration, and duration of drug therapy;

(iii) special directions and precautions for preparation, administration, and use by the patient;

(iv) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(v) techniques for self monitoring of drug therapy;

(vi) proper storage;

(vii) refill information; and

(viii) action to be taken in the event of a missed dose.

(B) Such communication:

(i) shall be provided with each new prescription drug order;

(ii) shall be provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent;

(iii) shall be communicated orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits such oral communication; and

(iv) shall be reinforced with written information. The following is applicable concerning this written information.

(I) Written information designed for the consumer such as the USP DI patient information leaflets shall be provided.

(II) When a compounded product is dispensed, information shall be provided for the major active ingredient(s), if available.

(III) For new drug entities, if no written information is initially available, the pharmacist is not required to provide information until such information is available, provided:

(-a-) the pharmacist informs the patient or the patient's agent that the product is a new drug entity and written information is not available;

(-b-) the pharmacist documents the fact that no written information was provided; and

(-c-) if the prescription is refilled after written information is available, such information is provided to the patient or patient's agent.

(C) Only a pharmacist may verbally provide drug information to a patient or patient's agent and answer questions concerning

prescription drugs. Non-pharmacist personnel may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(D) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide consultation when a patient or patient's agent refuses such consultation. The pharmacist shall document such refusal for consultation.

(E) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient at the pharmacy, the following is applicable.

(i) So that a patient will have access to information concerning his or her prescription, a prescription may not be delivered to a patient unless a pharmacist is in the pharmacy, except as provided in subsection (b)(3) of this section. [~~or clause (ii) of this subparagraph.~~]

~~*[(ii)* An agent of the pharmacist may deliver a prescription drug order to the patient or his or her agent during short periods of time when a pharmacist is absent from the pharmacy, provided the short periods of time do not exceed two hours in a 24 hour period, and provided a record of the delivery is maintained containing the following information:]~~

~~*[(I)* date of the delivery;]~~

~~*[(II)* unique identification number of the prescription drug order;]~~

~~*[(III)* patient's name;]~~

~~*[(IV)* patient's phone number or the phone number of the person picking up the prescription; and]~~

~~*[(V)* signature of the person picking up the prescription.]~~

(ii) [~~(iii)~~] Any prescription delivered to a patient when a pharmacist is not in the pharmacy must meet the requirements described in subparagraph (F) of this paragraph.

(iii) [~~(iv)~~] A Class A pharmacy shall make available for use by the public a current or updated edition of the United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient), or another source of such information designed for the consumer.

(F) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient or his or her agent at the patient's residence or other designated location, the following is applicable.

(i) The information specified in subparagraph (A) of this paragraph shall be delivered with the dispensed prescription in writing.

(ii) If prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacy shall provide a toll-free telephone line which is answered during normal business hours to enable communication between the patient and a pharmacist.

(iii) The pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container in both English and Spanish the local and if applicable, toll-free telephone number of the pharmacy and the statement: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."

(iv) The pharmacy shall maintain and use adequate storage or shipment containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

(v) The pharmacy shall use a delivery system which is designed to assure that the drugs are delivered to the appropriate patient.

(G) Except as specified in subparagraph (B) of this paragraph, in the best interest of the public health and to optimize drug therapy, upon delivery of a refill prescription, a pharmacist shall ensure that the patient or patient's agent is offered information about the refilled prescription. Either a pharmacist or other pharmacy personnel shall inform the patient or patient's agent that a pharmacist is available to discuss the patient's prescription and provide information.

(H) A pharmacy shall post a sign no smaller than 8.5 inches by 11 inches in clear public view at all locations in the pharmacy where a patient may pick up prescriptions. The sign shall contain the following statement in a font that is easily readable: "Do you have questions about your prescription? Ask the pharmacist." Such notification shall be in both English and Spanish.

(I) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).

(2) - (5) (No change.)

(6) Prescription containers.

(A) A drug dispensed pursuant to a prescription drug order shall be dispensed in a child-resistant container unless:

(i) the patient or the practitioner requests the prescription not be dispensed in a child-resistant container; or

(ii) the product is exempted from requirements of the Poison Prevention Packaging Act of 1970.

(B) A drug dispensed pursuant to a prescription drug order shall be dispensed in an appropriate container as specified on the manufacturer's container.

(C) Prescription containers or closures shall not be re-used. However, if a patient or patient's agent has difficulty reading or understanding a prescription label, a prescription container may be reused provided:

(i) the container is designed to provide audio-recorded information about the proper use of the prescription medication;

(ii) the container is reused for the same patient;

(iii) the container is cleaned; and

(iv) a new safety closure is used each time the prescription container is reused.

(7) - (8) (No change.)

(d) - (g) (No change.)

(h) Customized patient medication packages.

(1) - (2) (No change.)

(3) Label.

(A) The patient med-pak shall bear a label stating:

(i) the name of the patient;

(ii) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(iii) the name, strength, physical description or identification, and total quantity of each drug product contained therein;

(iv) the directions for use and cautionary statements, if any, contained in the prescription drug order for each drug product contained therein;

(v) if applicable, a warning of the potential harmful effect of combining any form of alcoholic beverage with any drug product contained therein;

(vi) any storage instructions or cautionary statements required by the official compendia;

(vii) the name of the prescriber of each drug product;

(viii) the date of preparation of the patient med-pak and the beyond-use date assigned to the patient med-pak (which such beyond-use date shall not be later than 60 days from the date of preparation);

(ix) the name, address, and telephone number of the pharmacy;

(x) the initials or an identification code of the dispensing pharmacist; and

(xi) any other information, statements, or warnings required for any of the drug products contained therein.

(B) If the patient med-pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying each of the drug product contained therein.

(C) The dispensing container is not required to bear the label specified in subparagraph (A) of this paragraph if:

(i) the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital);

(ii) no more than a 34-day supply or 100 dosage units, whichever is less, is dispensed at one time;

(iii) the drug is not in the possession of the ultimate user prior to administration;

(iv) the pharmacist-in-charge has determined that the institution:

(I) maintains medication administration records which include adequate directions for use for the drug(s) prescribed;

(II) maintains records of ordering, receipt, and administration of the drug(s); and

(III) provides for appropriate safeguards for the control and storage of the drug(s); and

(v) the dispensing container bears a label that [~~the system employed by the pharmacy in dispensing the prescription drug order~~] adequately:

(I) identifies the:

(-a-) pharmacy by name and address;

(-b-) unique identification number of the prescription;

(-c-) name and strength of each drug product dispensed;

(-d-) name of the patient;

(-e-) name of the prescribing practitioner of each drug productand if applicable, the name of the advanced practice nurse or physician assistant who signed the prescription drug order; and

(II) for each drug product sets forth the directions for use and cautionary statements, if any, contained on the prescription drug order or required by law.

(4) - (7) (No change.)

§291.34. Records.

(a) Maintenance of records.

(1) Every inventory or other record required to be kept under the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Requirements), contained in Community Pharmacy (Class A) shall be:

(A) kept by the pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(2) - (4) (No change.)

(b) Prescriptions.

(1) - (6) (No change.)

(7) Refills.

(A) Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order.

(B) If there are no refill instructions on the original prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original prescription drug order have been dispensed, authorization from the prescribing practitioner shall be obtained prior to dispensing any refills.

(C) Refills of prescription drug orders for dangerous drugs or nonprescription drugs.

(i) Prescription drug orders for dangerous drugs or nonprescription drugs may not be refilled after one year from the date of issuance of the original prescription drug order.

(ii) If one year has expired from the date of issuance of an original prescription drug order for a dangerous drug or nonprescription drug, authorization shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of the drug.

(D) Refills of prescription drug orders for Schedules III - V controlled substances.

(i) Prescription drug orders for Schedules III - V controlled substances may not be refilled more than five times or after

six months from the date of issuance of the original prescription drug order, whichever occurs first.

(ii) If a prescription drug order for a Schedule III, IV, or V controlled substance has been refilled a total of five times or if six months have expired from the date of issuance of the original prescription drug order, whichever occurs first, a new and separate prescription drug order shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of controlled substances.

(E) A pharmacist may exercise his professional judgment in refilling a prescription drug order for a drug, other than a controlled substance listed in Schedule II, without the authorization of the prescribing practitioner, provided:

(i) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(ii) either:

(I) a natural or manmade disaster has occurred which prohibits the pharmacist from being able to contact the practitioner; or

(II) the pharmacist is unable to contact the practitioner after a reasonable effort;

(iii) the quantity of prescription drug dispensed does not exceed a 72-hour supply;

(iv) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided without such authorization and that authorization of the practitioner is required for future refills;

(v) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable time;

(vi) the pharmacist maintains a record of the emergency refill containing the information required to be maintained on a prescription as specified in this subsection;

(vii) the pharmacist affixes a label to the dispensing container as specified in §291.33(c)(7) [~~§291.33(c)(6)~~] of this title; and

(viii) if the prescription was initially filled at another pharmacy, the pharmacist may exercise his professional judgment in refilling the prescription provided:

(I) the patient has the prescription container, label, receipt or other documentation from the other pharmacy which contains the essential information;

(II) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription;

(III) the pharmacist, in his professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of clauses (i) and (ii) of this subparagraph; and

(IV) the pharmacist complies with the requirements of clauses (iii) - (v) of this subparagraph.

(c) (No change.)

(d) Prescription drug order records maintained in a manual system.

(1) - (5) (No change.)

(6) Effective January 1, 2009, each time a modification, change, or manipulation is made to a record of dispensing, documentation of such change shall be recorded on the back of the prescription or on another appropriate, uniformly maintained, readily retrievable record, such as [~~a~~]medication records. The documentation of any modification, change, or manipulation to a record of dispensing shall include the identification of the individual responsible for the alteration.

(e) Prescription drug order records maintained in a data processing system.

(1) - (3) (No change.)

(4) Transfer of prescription drug order information. For the purpose of refill or initial dispensing, the transfer of original prescription drug order information is permissible between pharmacies, subject to the following requirements.

(A) The transfer of original prescription drug order information for controlled substances listed in Schedule III, IV, or V is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(B) The transfer of original prescription drug order information for dangerous drugs is permissible between pharmacies without limitation up to the number of originally authorized refills.

(C) The transfer is communicated directly between pharmacists and/or pharmacist interns orally by telephone or via facsimile or as authorized in paragraph (5) of this subsection. A transfer completed as authorized in paragraph (5) of this subsection may be initiated by a pharmacy technician or pharmacy technician trainee acting under the direct supervision of a pharmacist.

(D) Both the original and the transferred prescription drug orders are maintained for a period of two years from the date of last refill.

(E) The pharmacist or pharmacist intern transferring the prescription drug order information shall:

(i) write the word "void" on the face of the invalidated prescription drug order; and

(ii) record on the reverse of the invalidated prescription drug order the following information:

(I) the name, address, and if a controlled substance, the DEA registration number of the pharmacy to which such prescription is transferred;

(II) the name of the pharmacist or pharmacist intern receiving the prescription drug order information;

(III) the name of the pharmacist or pharmacist intern transferring the prescription drug order information; and

(IV) the date of the transfer.

(F) The pharmacist or pharmacist intern receiving the transferred prescription drug order information shall:

(i) write the word "transfer" on the face of the transferred prescription drug order; and

(ii) record on the transferred prescription drug order the following information:

(I) original date of issuance and date of dispensing or receipt, if different from date of issuance;

(II) original prescription number and the number of refills authorized on the original prescription drug order;

(III) number of valid refills remaining and the date of last refill, if applicable;

(IV) name, address, and if a controlled substance, the DEA registration number of the pharmacy from which such prescription drug order information is transferred; and

(V) name of the pharmacist or pharmacist intern transferring the prescription drug order information.

(G) Prescription drug orders may not be transferred by non-electronic means during periods of downtime except on consultation with and authorization by a prescribing practitioner; provided however, during downtime, a hard copy of a prescription drug order may be made available for informational purposes only, to the patient, a pharmacist or pharmacist intern, and the prescription may be read to a pharmacist or pharmacist intern by telephone.

(H) The original prescription drug order shall be invalidated in the data processing system for purposes of filling or refilling, but shall be maintained in the data processing system for refill history purposes.

(I) If the data processing system has the capacity to store all the information required in subparagraphs (E) and (F) of this paragraph, the pharmacist is not required to record this information on the original or transferred prescription drug order.

(J) The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance prescription drug orders which have been previously transferred.

(5) Electronic transfer of prescription drug order information between pharmacies. Pharmacies electronically accessing the same prescription drug order records may electronically transfer prescription information if the following requirements are met.

(A) The original prescription is voided and the following information is documented in the records of the transferring pharmacy:

(i) the name, address, and if a controlled substance, the DEA registration number of the pharmacy to which such prescription is transferred;

(ii) the name of the pharmacist or pharmacist intern receiving the prescription drug order information; and

(iii) the date of the transfer.

(B) Pharmacies not owned by the same person may electronically access the same prescription drug order records, provided the owner or chief executive officer of each pharmacy signs an agreement allowing access to such prescription drug order records.

(C) An electronic transfer between pharmacies may be initiated by a pharmacy technician or pharmacy technician trainee acting under the direct supervision of a pharmacist.

(6) (No change.)

(f) - (j) (No change.)

~~[(k) Confidentiality.]~~

~~[(1) A pharmacist shall provide adequate security of prescription drug orders, and patient medication records to prevent indiscriminate or unauthorized access to confidential health information. If prescription drug orders, requests for refill authorization, or other confidential health information are not transmitted directly between a pharmacy and a physician but are transmitted through a data communication device, confidential health information may not be accessed or maintained by the operator of the data communication device unless specifically authorized to obtain the confidential information by this subsection.]~~

~~[(2) Confidential records are privileged and may be released only to:]~~

~~[(A) the patient or the patient's agent;]~~

~~[(B) a practitioner or another pharmacist if, in the pharmacist's professional judgement, the release is necessary to protect the patient's health and well being;]~~

~~[(C) the board or to a person or another state or federal agency authorized by law to receive the confidential record;]~~

~~[(D) a law enforcement agency engaged in investigation of a suspected violation of Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.);]~~

~~[(E) a person employed by a state agency that licenses a practitioner, if the person is performing the person's official duties; or]~~

~~[(F) an insurance carrier or other third party payor authorized by a patient to receive such information.]~~

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702212
Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 305-8028

22 TAC §291.37, §291.38

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the offices of the Texas State Board of Pharmacy or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by the repeal: Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.37. Centralized Prescription Dispensing.

§291.38. Central Prescription Drug or Medication Order Processing.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702213

Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 305-8028

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SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)

22 TAC §§291.72 - 291.76

The Texas State Board of Pharmacy proposes amendments to §291.72 concerning Definitions, §291.73 concerning Personnel, §291.74 concerning Operational Standards, §291.75 concerning Records, and §291.76 concerning Pharmacies Located in a Freestanding Ambulatory Surgical Center. The proposed amendments to §291.72, if adopted, clarify the definition for hot water and update and clarify the definitions for pharmacy technicians and pharmacy technician trainees. The proposed amendments to §291.73, if adopted, update the rules to include pharmacy technician trainees and clarify the responsibilities of owners of Class C pharmacies. The proposed amendments to §291.74, if adopted, will allow Class C pharmacies to distribute repackaged drugs to other Class C pharmacies under common ownership in accordance with SB 492 passed by the 79th Texas Legislature, Regular Session. The proposed amendments to §291.75, if adopted, require pharmacies to provide the board or its representative with records in electronic format, if the records are maintained in an electronic format, and update and correct references. The proposed amendments to §291.76, if adopted, update and clarify the definitions for pharmacy technicians and pharmacy technician trainees and clarify the responsibilities of owners of pharmacies located in ambulatory surgical centers.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the rule will be to ensure that the rules are up to date and clear and the public benefit anticipated as a result of enforcing §291.74 will be to ensure that drugs prepackaged and distributed by a Class C pharmacy to another Class C pharmacy under common ownership are handled in a manner to ensure the health and safety of the public. There is no fiscal impact for individuals, small or large businesses or to other entities which are required to comply with this section.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas, 78701, FAX (512) 305-8082. Comments must be received by 5 pm, July 30, 2007.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by the amendments: Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.72. Definitions.

The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.

(1) - (24) (No change.)

(25) Hot water--The temperature of water from the pharmacy's sink maintained at 120 to 140 degrees F (49 to 60 C).

(26) [~~(25)~~] Inpatient--A person who is duly admitted to the licensed hospital, or other hospital or facility maintained or operated by the state, or who is receiving long term care services or Medicare extended care services in a swing bed on the hospital premise or an adjacent, readily accessible facility which is under the authority of the hospital's governing body. For the purposes of this definition, the term "long term care services" means those services received in a skilled nursing facility which is a distinct part of the hospital and the distinct part is not licensed separately or formally approved as a nursing home by the state, even though it is designated or certified as a skilled nursing facility. An inpatient includes a person confined in any correctional institution operated by the state of Texas.

(27) [~~(26)~~] Institutional pharmacy--Area or areas in a facility where drugs are stored, bulk compounded, delivered, compounded, dispensed, and distributed to other areas or departments of the facility, or dispensed to an ultimate user or his or her agent.

(28) [~~(27)~~] Investigational new drug--New drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the Food and Drug Administration.

(29) [~~(28)~~] Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

(30) [~~(29)~~] Medication order--A written order from a practitioner or a verbal order from a practitioner or his authorized agent for administration of a drug or device.

(31) [~~(30)~~] Part-time pharmacist--A pharmacist either employed or under contract, who routinely works less than full-time.

(32) [~~(31)~~] Perpetual inventory--An inventory which documents all receipts and distributions of a drug product, such that an accurate, current balance of the amount of the drug product present in the pharmacy is indicated.

(33) [~~(32)~~] Pharmaceutical care--The provision of drug therapy and other pharmaceutical services intended to assist in the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

(34) [~~(33)~~] Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(35) [~~(34)~~] Pharmacy and therapeutics function--Committee of the medical staff in the facility which assists in the formulation of broad professional policies regarding the evaluation, selection, distribution, handling, use, and administration, and all other matters relating to the use of drugs and devices in the facility.

(36) [~~(35)~~] Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible

to a pharmacist. [~~Pharmacy technician includes registered pharmacy technicians and pharmacy technician trainees.~~]

(37) [~~(36)~~] Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

[~~(A) not registered as a pharmacy technician by the board, and either:~~]

[~~(B) participating in a pharmacy's technician training program; or~~]

[~~(C) currently enrolled in a:~~]

[~~*(i)* pharmacy technician training program accredited by the American Society of Health-System Pharmacists; or~~]

[~~*(ii)* health science technology education program in a Texas high school that is accredited by the Texas Education Agency.~~]

(38) [~~(37)~~] Pre-packaging--The act of re-packaging and re-labeling quantities of drug products from a manufacturer's original container into unit-dose packaging or a multiple dose container for distribution within the facility.

(39) [~~(38)~~] Prescription drug--

(A) A substance for which federal or state law requires a prescription before it may be legally dispensed to the public;

(B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend that complies with federal law; or

(ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or

(C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

(40) [~~(39)~~] Prescription drug order--

(A) a written order from a practitioner or a verbal order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) a written order or a verbal order pursuant to Subtitle B, Chapter 157, Occupations Code.

(41) [~~(40)~~] Quality assurance--The set of activities used to assure that the process used in the preparation of sterile drug products lead to products that meet predetermined standards of quality.

(42) [~~(41)~~] Quality control--The set of testing activities used to determine that the ingredients, components (e.g., containers), and final sterile pharmaceuticals prepared meet predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.

(43) [~~(42)~~] Sample--A prescription drug which is not intended to be sold and is intended to promote the sale of the drug.

(44) [~~(43)~~] Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and Safety Code, Chapter 481, as amended.

(45) [~~(44)~~] Unit-dose packaging--The ordered amount of drug in a dosage form ready for administration to a particular patient, by the prescribed route at the prescribed time, and properly labeled with name, strength, and expiration date of the drug.

(46) [~~(45)~~] Unusable drugs--Drugs or devices that are unusable for reasons, such as they are adulterated, misbranded, expired, defective, or recalled.

(47) [~~(46)~~] Written protocol--A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas State Board of Medical Examiners under the Texas Medical Practice Act Subtitle B, Chapter 157, Occupations Code.

§291.73. Personnel.

(a) (No change.)

(b) Pharmacist-in-charge.

(1) General.

(A) Each institutional pharmacy in a facility with 101 beds or more shall have one full-time pharmacist-in-charge, who may be pharmacist-in-charge for only one such pharmacy.

(B) Each institutional pharmacy in a facility with 100 beds or less shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis, if desired, and who may be pharmacist-in-charge for no more than three facilities or 150 beds.

(C) A pharmacist-in-charge may be in charge of one facility with 101 beds or more and one facility with 100 beds or less provided the total number of beds does not exceed 150 beds.

(D) The pharmacist-in-charge shall be assisted by additional pharmacists, pharmacy technicians and pharmacy technician trainees [~~and pharmacy technicians~~] commensurate with the scope of services provided.

(E) If the pharmacist-in-charge is employed on a part-time or consulting basis, a written agreement shall exist between the facility and the pharmacist, and a copy of the written agreement shall be made available to the board upon request.

(2) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following:

(A) providing the appropriate level of pharmaceutical care services to patients of the facility;

(B) ensuring that drugs and/or devices are prepared for distribution safely, and accurately as prescribed;

(C) providing written guidelines and approval of the procedure to assure that all pharmaceutical requirements are met when any part of preparing, sterilizing, and labeling of sterile preparations [~~pharmaceuticals~~] is not performed under direct pharmacy supervision;

(D) participating in the development of a formulary for the facility, subject to approval of the appropriate committee of the facility;

(E) developing a system to assure that drugs to be administered to inpatients are distributed pursuant to an original or direct copy of the practitioner's medication order;

(F) developing a system for the filling and labeling of all containers from which drugs are to be distributed or dispensed;

(G) assuring that the pharmacy maintains and makes available a sufficient inventory of antidotes and other emergency drugs as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations,

and such other materials and information as may be deemed necessary by the appropriate committee of the facility;

(H) maintaining records of all transactions of the institutional pharmacy as may be required by applicable law, state and federal, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials including pharmaceuticals, components used in the compounding of pharmaceuticals, and drug delivery devices;

(I) participating in those aspects of the facility's patient care evaluation program which relate to pharmaceutical utilization and effectiveness;

(J) participating in teaching and/or research programs in the facility;

(K) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the facility;

(L) providing effective and efficient messenger or delivery service to connect the institutional pharmacy with appropriate areas of the facility on a regular basis throughout the normal workday of the facility;

(M) developing a system for the labeling, storage, and distribution of investigational new drugs, including maintenance of information in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of investigational new drugs;

(N) assuring that records in a data processing system are maintained such that the data processing system is in compliance with Class C (Institutional) pharmacy requirements;

(O) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(P) assuring the legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or rules governing the practice of pharmacy; and

(Q) if the pharmacy uses an automated medication supply system, shall be responsible for the following:

(i) reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(ii) inspecting medications in the automated medication supply system, at least monthly, for expiration date, misbranding, physical integrity, security, and accountability;

(iii) assigning, discontinuing, or changing personnel access to the automated medication supply system;

(iv) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed healthcare professionals performing any services in connection with an automated medication supply system have been properly trained on the use of the system and can demonstrate comprehensive knowledge of the written policies and procedures for operation of the system; and

(v) ensuring that the automated medication supply system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

(c) (No change.)

(d) Pharmacists.

(1) General.

(A) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the institutional pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.

(B) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in subsection (b)(2) of this section and in ordering, administering, and accounting for pharmaceutical materials.

(C) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or pharmacy technician trainees under his or her supervision.

(D) All pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(E) A distributing pharmacist shall ensure that the drug is prepared for distribution safely, and accurately as prescribed. In addition, if multiple pharmacists participate in the preparation of medication orders for distribution, each pharmacist shall ensure the safety and accuracy of the portion of the process the pharmacist is performing. The preparation and distribution process for medication orders shall include, but not be limited to, drug regimen review, and verification of accurate medication order data entry, preparation, and distribution, and performance of the final check of the prepared medication.

(2) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be limited to the following:

(A) providing those acts or services necessary to provide pharmaceutical care;

(B) receiving, interpreting, and evaluating prescription drug orders, and reducing verbal medication orders to writing either manually or electronically;

(C) participating in drug and/or device selection as authorized by law, drug and/or device supplier selection, drug administration, drug regimen review, or drug or drug-related research;

(D) performing a specific act of drug therapy management for a patient delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with the Medical Practice Act Subtitle B, Chapter 157, Occupations Code;

(E) accepting the responsibility for:

(i) distributing drugs and devices pursuant to medication orders;

(ii) compounding and labeling of drugs and devices;

(iii) proper and safe storage of drugs and devices; and

(iv) maintaining proper records for drugs and devices.

(3) Special requirements for compounding.

(A) Non-Sterile Preparations. [~~Pharmaceuticals.~~] All pharmacists engaged in compounding non-sterile preparations [~~pharmaceuticals~~] shall meet the training requirements specified in §291.131 [~~§291.25~~] of this title (relating to Pharmacies Compounding Non-sterile Preparations [~~Pharmaceuticals~~]).

(B) Sterile Preparations [~~Pharmaceuticals~~]. All pharmacists engaged in compounding sterile preparations [~~non-sterile pharmaceuticals~~] shall meet the training requirements specified in §291.133

[§291.26] of this title (relating to Pharmacies Compounding Sterile Preparations [Pharmaceuticals]).

(e) Pharmacy technicians and pharmacy technician trainees.

(1) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

[(A) On June 1, 2004, all persons employed as pharmacy technicians must be either registered pharmacy technicians or pharmacy technician trainees as follows.]

[(i) All persons who have passed the required pharmacy technician certification examination must be registered with the board under the provisions of this section.]

[(ii) All persons who have not taken and passed the required pharmacy certification examination shall be designated pharmacy technician trainees under the provisions of §297.5 of this title (relating to Pharmacy Technician Trainees).]

[(B) Between January 1, 2004, and May 31, 2004, all persons employed as pharmacy technicians who are qualified for registration by the board shall register according to the schedule designated by the board. Between January 1, 2004 and May 31, 2004, persons who are awaiting their scheduled time for registration and persons who have applied for registration, but the registration has not been completed shall comply with the rules in effect prior to January 1, 2004, relating to requirements and duties for certified or exempt pharmacy technicians.]

[(C) All pharmacy technicians shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician Training).]

(2) Duties. Duties may include, but need not be limited to, the following functions under the direct supervision of and responsible to a pharmacist:

(A) pre-packing and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her signature (first initial and last name or full signature) or electronic signature to the appropriate quality control records;

(B) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(C) bulk compounding or batch preparation provided a pharmacist supervises and conducts in-process and final checks and affixes his or her initials to the appropriate quality control records;

(D) distributing routine orders for stock supplies to patient care areas;

(E) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in §291.74(e) of this title (relating to Operational Standards);

(F) loading bulk unlabeled drugs into an automated compounding or counting device provided a pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his or her signature (first initial and last name or full signature) or electronic signature to the appropriate quality control records; and

(G) may be allowed access to automated medication supply systems after proper training on the use of the automated medication supply system and demonstration of comprehensive knowledge of the written policies and procedures for its operation.

(H) compounding sterile preparations [pharmaceuticals] pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees:

(i) have completed the training specified in §291.133 [§291.26] of this title (relating to Pharmacies Compounding Sterile Preparations [pharmaceuticals]; and

(ii) are supervised by a pharmacist who has completed the training specified in §291.133 [§291.26] of this title and who conducts in-process and final checks, and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not required on the label if it is maintained in a permanent record of the pharmacy.)

(3) Special requirements for compounding.

(A) Non-Sterile Preparations [Pharmaceuticals]. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations [pharmaceuticals] shall meet the training requirements specified in §291.131 [§291.25] of this title.

(B) Sterile Preparations [Pharmaceuticals]. Pharmacy technicians and pharmacy technician trainees engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title. [may compound sterile pharmaceuticals pursuant to medication orders provided the pharmacy technicians:]

[(i) have completed the training specified subsection §291.26 of this title; and]

[(ii) are supervised by a pharmacist who has completed the training specified in §291.26 of this title and who conducts in-process and final checks, and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not required on the label if it is maintained in a permanent record of the pharmacy).]

(4) Procedures.

(A) pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard, written procedures and guidelines.

(B) pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as those working in a Class A pharmacy.

(f) Owner. The owner of a Class C pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(1) establishment of policies for procurement of prescription drugs and devices and other products dispensed from the Class C pharmacy;

(2) establishment and maintenance of effective controls against the theft or diversion of prescription drugs;

(3) if the pharmacy uses an automated pharmacy dispensing system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(4) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(5) establishment of policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(g) [~~(f)~~] Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows. [~~wear an identification tag or badge which bears the person's name and identifies him or her by title or function as follows:~~]

(1) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that [~~which~~] bears the person's name and identifies him or her as a [~~pharmacy technician trainee, a registered~~] pharmacy technician, or a certified pharmacy technician, if the technician maintains current certification with the Pharmacy Technician Certification Board or any other entity providing an examination approved by the board. [~~Board.~~]

(2) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

(3) [~~(2)~~] Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that [~~which~~] bears the person's name and identifies him or her as a pharmacist intern.

(4) [~~(3)~~] Pharmacists. All pharmacists shall wear an identification tag or badge that [~~which~~] bears the person's name and identifies him or her as a pharmacist.

§291.74. Operational Standards.

(a) Licensing requirements.

(1) - (2) (No change.)

(3) A Class C pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications). [~~§291.4 of this title (relating to Change of Ownership).~~]

(4) A Class C pharmacy which changes location and/or name shall notify the board within 10 days of the change and file for an amended license as specified in §291.3 of this title (relating to Required Notifications). [~~§291.2 if this title (relating to Change of Location and/or Name).~~]

(5) A Class C pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change following the procedures in §291.3 of this title (relating to Required Notifications). [~~§291.3 of this title (relating to Change of Managing Officers).~~]

(6) - (9) (No change.)

(10) A Class C (Institutional) pharmacy engaged in non-sterile compounding of drug products for inpatients of the hospital shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-sterile Preparations); [~~§291.25 of this title (relating to Pharmacies Compounding Non-Sterile Pharmaceuticals);~~]

(11) A Class C (Institutional) pharmacy engaged in the compounding of sterile pharmaceuticals shall comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations). [~~§291.26 of this title (relating to Pharmacies Compounding Sterile Pharmaceuticals).~~]

(12) A Class C (Institutional) pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 [~~§291.20~~] of this title (relating to Remote Pharmacy Services).

(13) A Class C (Institutional) pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing). [~~§291.37 of this title (relating to Centralized Prescription Dispensing) and/or §291.38 of this title (relating to Centralized Prescription Drug or Medication Order Processing).~~]

(b) - (e) (No change.)

(f) Drugs.

(1) - (2) (No change.)

(3) Prepackaging of drugs.

(A) Distribution within a facility.

(i) Drugs may be prepackaged in quantities suitable for internal distribution by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(ii) The label of a prepackaged unit shall indicate:

(I) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(II) facility's unique lot number;

(III) expiration date based on currently available literature; and

(IV) quantity of the drug, if the quantity is greater than one.

(iii) Records of prepackaging shall be maintained to show:

(I) name of the drug, strength, and dosage form;

(II) facility's unique lot number;

(III) manufacturer or distributor;

(IV) manufacturer's lot number;

(V) expiration date;

(VI) quantity per prepackaged unit;

(VII) number of prepackaged units;

(VIII) date packaged;

(IX) name, initials, or electronic signature of the prepacker; and

(X) name, initials, or electronic signature of the responsible pharmacist.

(iv) Stock packages, prepackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(B) Distribution to other Class C (Institutional) pharmacies under common ownership.

(i) Drugs may be prepackaged in quantities suitable for distribution to other Class C (Institutional) pharmacies under com-

mon ownership by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(ii) The label of a prepackaged unit shall indicate:

(I) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(II) facility's unique lot number;

(III) expiration date based on currently available literature;

(IV) quantity of the drug, if the quantity is greater than one; and

(V) name of the facility responsible for pre-packaging the drug.

(iii) Records of pre-packaging shall be maintained to show:

(I) name of the drug, strength, and dosage form;

(II) facility's unique lot number;

(III) manufacturer or distributor;

(IV) manufacturer's lot number;

(V) expiration date;

(VI) quantity per prepackaged unit;

(VII) number of prepackaged units;

(VIII) date packaged;

(IX) name, initials, or electronic signature of the prepacker;

(X) name, initials, or electronic signature of the responsible pharmacist; and

(XI) name of the facility receiving the pre-packaged drug.

(iv) Stock packages, prepackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(v) The pharmacy shall have written procedure for the recall of any drug prepackaged for another Class C Pharmacy under common ownership. The recall procedures shall require:

(I) notification to the pharmacy to which the prepackaged drug was distributed;

(II) quarantine of the product if there is a suspicion of harm to a patient;

(III) a mandatory recall if there is confirmed or probable harm to a patient; and

(IV) notification to the board if a mandatory recall is instituted.

~~[(A) Drugs may be pre-packaged in quantities suitable for internal distribution only by a pharmacist or by supportive personnel under the direction and direct supervision of a pharmacist.]~~

~~[(B) The label of a pre-packaged unit shall indicate:]~~

~~*[(i)* brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;]~~

~~*[(ii)* facility's unique lot number;]~~

~~*[(iii)* expiration date based on currently available literature; and]~~

~~*[(iv)* quantity of the drug, if the quantity is greater than one.]~~

~~[(C) Records of pre-packaging shall be maintained to show:]~~

~~*[(i)* name of the drug, strength, and dosage form;]~~

~~*[(ii)* facility's unique lot number;]~~

~~*[(iii)* manufacturer or distributor;]~~

~~*[(iv)* manufacturer's lot number;]~~

~~*[(v)* expiration date;]~~

~~*[(vi)* quantity per prepackaged unit;]~~

~~*[(vii)* number of prepackaged units;]~~

~~*[(viii)* date packaged;]~~

~~*[(ix)* name, initials, or electronic signature of the prepacker; and]~~

~~*[(x)* name, initials, or electronic signature of the responsible pharmacist.]~~

~~[(D) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.]~~

(4) - (5) (No change.)

(g) - (i) (No change.)

(j) Automated devices and systems.

(1) (No change.)

(2) Automated medication supply systems.

(A) - (B) (No change.)

(C) Policies and procedures of operation.

(i) When an automated medication supply system is used to store or distribute medications for administration pursuant to medication orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall establish requirements for operation of the automated medication supply system and shall describe policies and procedures that:

(I) include a description of the policies and procedures of operation;

(II) provide for a pharmacist's review and approval of each original or new medication order filled through the use of the automated medication supply system:

(-a-) before the order is filled when a pharmacist is on duty except for an emergency order;

(-b-) retrospectively within 72 hours in a facility with a full-time pharmacist when a pharmacist is not on duty at the time the order is made; or

(-c-) retrospectively within 7 days in a facility with a part-time or consultant pharmacist when a pharmacist is not on duty at the time the order is made;

(III) provide for access to the automated medication supply system for stocking and retrieval of medications which is limited to licensed healthcare professionals, pharmacy technicians, or

pharmacy technician trainees [~~or pharmacy technicians~~] acting under the supervision of a pharmacist;

(IV) provide that a pharmacist is responsible for the accuracy of the restocking of the system. The actual restocking may be performed by a pharmacy technician or pharmacy technician trainee;

(V) provide for an accountability record to be maintained which documents all transactions relative to stocking and removing medications from the automated medication supply system;

(VI) require a prospective or retrospective drug regimen review is conducted as specified in subsection (g) of this section; and

(VII) establish and make provisions for documentation of a preventative maintenance program for the automated medication supply system.

(ii) A pharmacy which uses an automated medication supply system to fill medication orders shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(D) (No change.)

(3) (No change.)

(4) Automated checking device.

(A) For the purpose of this subsection, an automated checking device is a fully automated device which confirms, after a drug is prepared for distribution but prior to delivery to the patient, that the correct drug and strength has been labeled with the correct label for the correct patient.

(B) The final check of a drug prepared pursuant to a medication order shall be considered accomplished using an automated checking device provided:

(i) a check of the final product is conducted by a pharmacist prior to delivery to the patient or the following checks are performed by a pharmacist:

(I) the prepackaged drug used to fill the order is checked by a pharmacist who verifies that the drug is labeled and packaged accurately; and

(II) a pharmacist checks the accuracy of each original or new medication order.

(ii) the medication order is prepared, labeled, and made ready for delivery to the patient in compliance with Class C (Institutional) Pharmacy rules; and

(iii) prior to delivery to the patient:

(I) the automated checking device confirms that the correct drug and strength has been labeled with the correct label for the correct patient; and

(II) a pharmacist performs all other duties required to ensure that the medication order has been prepared safely and accurately as prescribed.

(C) If the final check is accomplished as specified in subparagraph (B) of this paragraph, the following additional requirements must be met.

(i) The pharmacy has conducted initial testing of the automated checking device and has a continuous quality assurance program which documents that the automated checking device accurately confirms that the correct drug and strength has been labeled with the correct label for the correct patient.

(ii) The pharmacy documents and maintains:

(I) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in subparagraph (B)(I) of this paragraph; and

(II) the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee [~~or pharmacy technician~~] who performs any other portion of the medication order preparation process.

(iii) The pharmacy establishes mechanisms and procedures to test the accuracy of the automated checking device at least monthly.

§291.75. Records.

(a) Maintenance of records.

(1) Every inventory or other record required to be kept under the provisions of §291.71 of this title (relating to Purpose), §291.72 of this title (relating to Definitions), §291.73 of this title (relating to Personnel), §291.74 of this title (relating to Operational Standards), and this section contained in Institutional Pharmacy (Class C) shall be:

(A) kept by the institutional pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative, and to other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(2) - (4) (No change.)

(b) - (f) (No change.)

[~~(g) Confidentiality.~~

[~~(1) A pharmacist shall provide adequate security of prescription drug orders, medication orders, and patient medication records to prevent indiscriminate or unauthorized access to confidential health information.~~]

[~~(2) Confidential records are privileged and may be released only to~~]

[~~(A) the patient or the patient's agent;~~]

[~~(B) a practitioner or another pharmacist if, in the pharmacist's professional judgement, the release is necessary to protect the patient's health and well being;~~]

[~~(C) the board or to a person or another state or federal agency authorized by law to receive the confidential record;~~]

[~~(D) a law enforcement agency engaged in investigation of a suspected violation of Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.);~~]

[~~(E) a person employed by a state agency that licenses a practitioner, if the person is performing the person's official duties; or~~]

[~~(F) an insurance carrier or other third party payor authorized by a patient to receive such information.~~]

§291.76. Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center.

(a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities, and operation of a pharmacy located in a freestanding ambulatory surgical center that is licensed by the Texas Department of State Health Services [~~Texas Department of Health~~]. Class C pharmacies located in a freestanding ambulatory surgical center shall comply with this section, in lieu of §§291.71 - 291.75 of this title (relating to Purpose; Definitions; Personnel; Operational Standards; and Records).

(b) Definitions. The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.

(1) - (22) (No change.)

(23) Pharmacy technician-- An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist. [~~Pharmacy technician includes registered pharmacy technicians and pharmacy technician trainees.~~]

(24) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program. [~~A person who is:~~]

[~~(A) not registered as a pharmacy technician by the board, and either:~~]

[~~(B) participating in a pharmacy's technician training program; or~~]

[~~(C) currently enrolled in a:~~]

[~~(i)~~ ~~pharmacy technician training program accredited by the American Society of Health-System Pharmacists; or~~]

[~~(ii)~~ ~~health science technology education program in a Texas high school that is accredited by the Texas Education Agency.~~]

(25) (No change.)

(c) Personnel.

(1) - (2) (No change.)

(3) Pharmacists.

(A) General.

(i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the ASC pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.

(ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for pharmaceutical materials.

(iii) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians under his or her supervision.

(iv) All pharmacists while on duty shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be limited to, the following:

(i) receiving and interpreting prescription drug orders and oral medication orders and reducing these orders to writing either manually or electronically;

(ii) selection of prescription drugs and/or devices and/or suppliers; and

(iii) interpreting patient profiles.

(C) Special requirements for compounding.

(i) Non-Sterile Preparations [~~Pharmaceuticals~~]. All pharmacists engaged in compounding non-sterile preparations [~~pharmaceuticals~~] shall meet the training requirements specified in §291.131 [~~§291.25~~] of this title (relating to Pharmacies Compounding Non-Sterile Preparations [~~Pharmaceuticals~~]).

(ii) Sterile Preparations [~~Pharmaceuticals~~]. All pharmacists engaged in compounding non-sterile preparations [~~pharmaceuticals~~] shall meet the training requirements specified in §291.133 [~~§291.26~~] of this title (relating to Pharmacies Compounding Sterile Preparations[~~Pharmaceuticals~~]).

(4) Pharmacy technicians and pharmacy technician trainees.

(A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

[~~(A) General~~]

[~~(i)~~ ~~On June 1, 2004, all persons employed as pharmacy technicians must be either registered pharmacy technicians or pharmacy technician trainees as follows.~~]

[~~(I)~~ ~~All persons who have passed the required pharmacy technician certification examination must be registered with the board under the provisions this section.~~]

[~~(II)~~ ~~All persons who have not taken and passed the required pharmacy certification examination shall be designated pharmacy technician trainees under the provisions of §297.5 of this title (relating to Pharmacy Technician Trainees).~~]

[~~(ii)~~ ~~Between January 1, 2004, and May 31, 2004, all persons employed as pharmacy technicians who are qualified for registration by the board shall register according to the schedule designated by the board. Between January 1, 2004 and May 31, 2004, persons who are awaiting their scheduled time for registration and persons who have applied for registration, but the registration has not been completed shall comply with the rules in effect prior to January 1, 2004, relating to requirements and duties for certified or exempt pharmacy technicians.~~]

[~~(iii)~~ ~~All pharmacy technicians shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician Training).~~]

(B) Duties. Duties may include, but need not be limited to, the following functions, under the direct supervision of a pharmacist:

(i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her signature or electronic signature to the appropriate quality control records;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(iii) compounding sterile preparations [~~pharmaceuticals~~] pursuant to medication orders; [~~provided the pharmacy technicians:~~]

~~*I(I)* have completed the training specified in §291.26 of this title (relating to Pharmacies Compounding Sterile Pharmaceuticals); and]~~

~~*I(II)* are supervised by a pharmacist who has completed the sterile products training specified in §291.26 of this title, conducts in-process and final checks, and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not required on the label if it is maintained in a permanent record of the pharmacy.)]~~

(iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her initials to the appropriate quality control records;

(v) distributing routine orders for stock supplies to patient care areas;

(vi) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section;

(vii) maintaining inventories of drug supplies;

(viii) maintaining pharmacy records; and

(ix) loading bulk unlabeled drugs into an automated drug dispensing system provided a pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his or her signature or electronic signature to the appropriate quality control records.

(C) Procedures.

(i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard written procedures and guidelines.

(ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as pharmacy technicians working in a Class A pharmacy.

(D) Special requirements for compounding.

(i) Non-Sterile Preparations [~~Pharmaceuticals~~]. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations [~~pharmaceuticals~~] shall meet the training requirements specified in §291.131 [~~§291.25~~] of this title.

(ii) Sterile Preparations [~~Pharmaceuticals~~]. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title. [~~Pharmacy technicians may compound sterile pharmaceuticals pursuant to medication orders provided the pharmacy technicians:~~]

~~*I(I)* have completed the training specified in §291.26 of this title; and]~~

~~*I(II)* are supervised by a pharmacist who has completed the training specified in §291.26 of this title and who conducts in-process and final checks, and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not required on the label if it is maintained in a permanent record of the pharmacy).]~~

(5) Owner. The owner of an ASC pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(A) establishment of policies for procurement of prescription drugs and devices and other products dispensed from the ASC pharmacy;

(B) establishment and maintenance of effective controls against the theft or diversion of prescription drugs;

(C) if the pharmacy uses an automated pharmacy dispensing system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(D) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(E) establishment of policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(6) [~~(5)~~] Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows: [~~wear an identification tag or badge which bears the person's name and identifies him or her by title or function as follows:~~]

(A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that [~~which~~] bears the person's name and identifies him or her as a pharmacy technician trainee a registered pharmacy technician, or a certified pharmacy technician, if the technician maintains current certification with the Pharmacy Technician Certification Board or any other entity providing an examination approved by the board[~~Board~~].

(B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

(C) [~~(B)~~] Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that [~~which~~] bears the person's name and identifies him or her as a pharmacist intern.

(D) [~~(C)~~] Pharmacists. All pharmacists shall wear an identification tag or badge that [~~which~~] bears the person's name and identifies him or her as a pharmacist.

(d) Operational standards.

(1) Licensing requirements.

(A) An ASC pharmacy shall register annually with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(B) If the ASC pharmacy is owned or operated by a pharmacy management or consulting firm, the following conditions apply.

(i) The pharmacy license application shall list the pharmacy management or consulting firm as the owner or operator.

(ii) The pharmacy management or consulting firm shall obtain DEA and DPS controlled substances registrations that are issued in the name of the firm, unless the following occur:

(I) the pharmacy management or consulting firm and the facility cosign a contractual pharmacy service agreement which assigns overall responsibility for controlled substances to the facility; and

(II) such pharmacy management or consulting firm maintains dual responsibility for the controlled substances.

(C) An ASC pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications). [~~§291.4 of this title (relating to Change of Ownership).~~]

(D) An ASC pharmacy which changes location and/or name shall notify the board of the change within 10 days and file for an amended license as specified in §291.3 of this title (relating to Required Notifications). [~~§291.2 of this title (relating to Change of Location and/or Name).~~]

(E) An ASC pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change, following the procedures in §291.3 of this title (relating to Required Notifications [~~Change of Managing Officers~~]).

(F) An ASC pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closed Pharmacies).

(G) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for issuance and renewal of a license and the issuance of an amended license.

(H) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(I) An ASC pharmacy, licensed under the Act, §560.051(a)(3), concerning institutional pharmacy (Class C), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class A), or the Act, §560.051(a)(2), concerning nuclear pharmacy (Class B), is not required to secure a license for the other type of pharmacy; provided, however, such license is required to comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Records), or §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy.

(J) An ASC pharmacy engaged in non-sterile compounding of drug products for inpatients of the hospital shall comply with the provisions of §291.131 [~~§291.25~~] of this title (relating to Pharmacies Compounding Non-Sterile Preparations [~~Pharmaceuticals~~]).

(K) An ASC pharmacy engaged in the compounding of sterile pharmaceuticals shall comply with the provisions of §291.133 [~~§291.26~~] of this title (relating to Pharmacies Compounding Sterile Preparations [~~Pharmaceuticals~~]).

(L) An ASC pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 [~~§291.20~~] of this title (relating to Remote Pharmacy Services).

(M) An ASC pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing). [~~§291.37 of this title (relating to Centralized Prescription Dispensing) and/or §291.38 of this title (relating to Centralized Prescription Drug or Medication Order Processing).~~]

(2) - (3) (No change.)

(4) Library. A reference library shall be maintained which includes the following in hard-copy or electronic format:

(A) current copies of the following:

(i) Texas Pharmacy Act and rules;

(ii) Texas Dangerous Drug Act and rules;

(iii) Texas Controlled Substances Act and rules;

(iv) Federal Controlled Substances Act and rules or official publication describing the requirements of the Federal Controlled Substances Act and rules;

(B) at least one current or updated reference from each of the following categories:

(i) Drug interactions. A reference text on drug interactions, such as Drug Interaction Facts. A separate reference is not required if other references maintained by the pharmacy contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken;

(ii) General information. A general information reference text, such as:

(I) Facts and Comparisons with current supplements;

(II) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the Healthcare Provider);

(III) AHFS Drug Information with current supplements;

(IV) Remington's Pharmaceutical Sciences; or

(V) Clinical Pharmacology;

(C) a current or updated reference on injectable drug products, such as Handbook of Injectable Drugs;

(D) basic antidote information and the telephone number of the nearest regional poison control center.

(E) if the pharmacy compounds sterile preparations [~~pharmaceuticals~~], specialty references appropriate for the scope of services provided by the pharmacy, e.g., if the pharmacy prepares cytotoxic drugs, a reference text on the preparation of cytotoxic drugs, such as Procedures for Handling Cytotoxic Drugs.

(F) metric-apothecary weight and measure conversion charts.

(5) Drugs.

(A) Procurement, preparation, and storage.

(i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff of the facility, relative to such responsibility.

(ii) The pharmacist-in-charge shall have the responsibility for determining specifications of all drugs procured by the facility.

(iii) ASC pharmacies may not sell, purchase, trade, or possess prescription drug samples, unless the pharmacy meets all of the following conditions:

(I) the pharmacy is owned by a charitable organization described in the Internal Revenue Code of 1986, or by a city, state or county government;

(II) the pharmacy is a part of a health care entity which provides health care primarily to indigent or low income patients at no or reduced cost;

(III) the samples are for dispensing or provision at no charge to patients of such health care entity; and

(IV) the samples are possessed in compliance with the federal Prescription Drug Marketing Act of 1986.

(iv) [~~(iii)~~] All drugs shall be stored at the proper temperatures, as defined by the following terms.

(I) Room temperature--temperature maintained between 15 degrees Celsius (59 degrees Fahrenheit) and 30 degrees Celsius (86 degrees Fahrenheit).

(II) Cool--temperature between 8 degrees Celsius (46 degrees Fahrenheit) and 15 degrees Celsius (59 degrees Fahrenheit). An article for which storage in a cool place is directed may, alternatively, be stored in a refrigerator unless otherwise specified on the labeling. [~~which may, alternatively, be stored in a refrigerator unless otherwise specified on the labeling.~~]

(III) Refrigerate--temperature that is thermostatically maintained between 2 degrees Celsius (36 degrees Fahrenheit) and 8 degrees Celsius (46 degrees Fahrenheit).

(IV) Freeze--temperature that is thermostatically maintained between minus [-] 20 degrees Celsius (minus [-] 4 degrees Fahrenheit) and minus [-] 10 degrees Celsius (14 degrees Fahrenheit).

(v) [~~(iv)~~] Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug.

(vi) [~~(v)~~] Outdated drugs shall be removed from dispensing stock and shall be quarantined together until such drugs are disposed of.

(B) Formulary.

(i) A formulary may be developed by an appropriate committee of the ambulatory surgical center.

(ii) The pharmacist-in-charge or consultant pharmacist shall be a full voting member of any committee which involves pharmaceutical services.

(C) Prepackaging of drugs and loading of bulk unlabeled drugs into automated drug dispensing system.

(i) Prepackaging of drugs.

(I) Drugs may be prepackaged in quantities suitable for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(II) The label of a prepackaged unit shall indicate:

(-a-) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(-b-) facility's lot number;

(-c-) expiration date; and

(-d-) quantity of the drug, if quantity is greater than one.

(III) Records of prepackaging shall be maintained to show:

(-a-) the name of the drug, strength, and dosage form;

(-b-) facility's lot number;

(-c-) manufacturer or distributor;

(-d-) manufacturer's lot number;

(-e-) expiration date;

(-f-) quantity per prepackaged unit;

(-g-) number of prepackaged units;

(-h-) date packaged;

(-i-) name, initials, or electronic signature of the prepacker; and

(-j-) signature or electronic signature of the responsible pharmacist.

(IV) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(ii) Loading bulk unlabeled drugs into automated drug dispensing systems.

(I) Automated drug dispensing systems may be loaded with bulk unlabeled drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(II) The label of an automated drug dispensing system container shall indicate the brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor.

(III) Records of loading bulk unlabeled drugs into an automated drug dispensing system shall be maintained to show:

(-a-) name of the drug, strength, and dosage form;

(-b-) manufacturer or distributor;

(-c-) manufacturer's lot number;

(-d-) expiration date;

(-e-) date of loading;

(-f-) name, initials, or electronic signature of the person loading the automated drug dispensing system; and

(-g-) signature or electronic signature of the responsible pharmacist.

(IV) The automated drug dispensing system shall not be used until a pharmacist verifies that the system is properly loaded and affixes his or her signature or electronic signature to the record specified in subclause (III) of this clause.

(6) Medication orders.

(A) Drugs may be administered to patients in ASCs only on the order of a practitioner. No change in the order for drugs may be made without the approval of a practitioner.

(B) Drugs may be distributed only pursuant to the original or a direct copy of the practitioner's medication order.

(C) Pharmacy technicians and pharmacy technician trainees may not receive oral medication orders.

(D) ASC pharmacies shall be exempt from the labeling provisions and patient notification requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication orders.

(E) In ASCs with a full-time pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the facility when the pharmacy is closed, the following is applicable.

(i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of a patient may be removed from the ASC pharmacy.

(ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

(iii) A record shall be made at the time of withdrawal by the authorized person removing the drugs and devices. The record shall contain the following information:

(I) name of the patient;

(II) name of device or drug, strength, and dosage form;

(III) dose prescribed;

(IV) quantity taken;

(V) time and date; and

(VI) signature or electronic signature of person making withdrawal.

(iv) The original or direct copy of the medication order may substitute for such record, provided the medication order meets all the requirements of clause (iii) of this subparagraph.

(v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more than 72 hours from the time of such withdrawal.

(F) In ASCs with a part-time or consultant pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the ASC when the pharmacist is not on duty, or when the pharmacy is closed, the following is applicable.

(i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be removed from the ASC pharmacy.

(ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

(iii) A record shall be made at the time of withdrawal by the authorized person removing the drugs and devices; the record shall meet the same requirements as specified in subparagraph (E)(iii) of this paragraph.

(iv) The pharmacist shall verify each distribution after a reasonable interval, but in no event may such interval exceed seven days.

(7) - (9) (No change.)

(e) Records.

(1) Maintenance of records.

(A) Every inventory or other record required to be kept under the provisions of §291.76 of this title (relating to Institutional Pharmacy (Class C)) shall be:

(i) kept by the pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative, and other authorized local, state, or federal law enforcement agencies; and

(ii) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(B) Records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy.

(C) Records of controlled substances listed in Schedules III - V shall be maintained separately or readily retrievable from all other records of the pharmacy. For purposes of this subsection, readily retrievable means that the controlled substances shall be asterisked, red-lined, or in some other manner readily identifiable apart from all other items appearing on the record.

(D) Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing or direct imaging system, e.g., microfilm or microfiche, provided:

(i) the records in the alternative data retention system contain all of the information required on the manual record; and

(ii) the alternative data retention system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(2) - (6) (No change.)

~~[(7) Confidentiality.]~~

~~[(A) A pharmacist shall provide adequate security of prescription drug orders, medication orders, and patient medication records to prevent indiscriminate or unauthorized access to confidential health information.]~~

~~[(B) Confidential records are privileged and may be released only to:]~~

~~*[(i)* the patient or the patient's agent;]~~

~~*[(ii)* a practitioner or another pharmacist if, in the pharmacist's professional judgement, the release is necessary to protect the patient's health and well being;]~~

~~*[(iii)* the board or to a person or another state or federal agency authorized by law to receive the confidential record;]~~

~~*[(iv)* a law enforcement agency engaged in investigation of a suspected violation of Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.);]~~

~~[(v)~~ ~~a person employed by a state agency that licenses a practitioner, if the person is performing the person's official duties; or]~~

~~[(vi)~~ ~~an insurance carrier or other third party payor authorized by a patient to receive such information.]~~

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

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Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 305-8028

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SUBCHAPTER E. CLINIC PHARMACY (CLASS D)

22 TAC §291.92

The Texas State Board of Pharmacy proposes amendments to §291.92 concerning Personnel. The proposed amendments to §291.92, if adopted, clarify the responsibilities of owners of Class D pharmacies.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the rule will be to clarify that owners are also responsible for the operation of a Class D pharmacy. There is no fiscal impact for individuals, small or large businesses or to other entities which are required to comply with this section.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas, 78701, FAX (512) 305-8082. Comments must be received by 5 pm, July 30, 2007.

The amendments are proposed under §551.002, and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by the amendments: Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.92. Personnel.

(a) - (d) (No change.)

(e) Owner. The owner of Class D pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(1) establishment of policies for procurement of prescription drugs and devices and other products provided or dispensed from the Class D pharmacy;

(2) establishment and maintenance of effective controls against the theft or diversion of prescription drugs;

(3) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(4) establishment of policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

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Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
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For further information, please call: (512) 305-8028

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SUBCHAPTER F. NON-RESIDENT PHARMACY (CLASS E)

22 TAC §291.104, §291.105

The Texas State Board of Pharmacy proposes amendments to §291.104, concerning Operational Standards and §291.105, concerning Records. The proposed amendments to §291.104 update references to other rules in this chapter and the proposed amendments to §291.105, if adopted, require pharmacies to provide the board or its representative with records in electronic format, if the records are maintained in an electronic format.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the amendments are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the amended sections.

Ms. Dodson has determined that, for each year of the first five-year period the amendments will be in effect, the public benefit anticipated as a result of enforcing the amended sections will be to ensure that the rules are up to date and clear in order to protect the public safety. There is no fiscal impact for individuals, small or large businesses or to other entities which are required to comply with the amended sections.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, FAX (512) 305-8082. Comments must be received by 5:00 p.m., July 30, 2007.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective

control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by the amendments: Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.104. Operational Standards.

(a) Licensing requirements.

(1) - (3) (No change.)

(4) A Class E pharmacy which changes ownership shall notify the board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications) [~~§291.4 of this title (relating to Change of Ownership)~~].

(5) A Class E pharmacy which changes location and/or name shall notify the board within ten days of the change and file for an amended license as specified in §291.3 of this title (relating to Required Notifications) [~~§291.2 of this title (relating to Change of Location and/or Name)~~].

(6) A Class E pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures in §291.3 of this title (relating to Required Notifications [~~Change of Managing Officers~~]).

(7) - (10) (No change.)

(11) A Class E pharmacy engaged in the centralized dispensing of prescription drug or medication orders shall comply with the provisions of §291.125 [~~§291.37~~] of this title (relating to Centralized Prescription Dispensing).

(12) A Class E pharmacy engaged in central processing of prescription drug or medication orders shall comply with the provisions of §291.123 [~~§291.38~~] of this title (relating to Central Prescription or Medication Order Processing).

(13) A Class E (Non-Resident) pharmacy engaged in the compounding of non-sterile preparations [~~pharmaceuticals~~] shall comply with the provisions of §291.131 [~~§291.25~~] of this title (relating to Pharmacies Compounding Non-Sterile Preparations [~~Pharmaceuticals~~]).

(14) A Class E (Non-Resident) pharmacy engaged in the compounding of sterile preparations [~~pharmaceuticals~~] shall comply with the provisions of §291.133 [~~§291.26~~] of this title (relating to Pharmacies Compounding Sterile Preparations [~~Pharmaceuticals~~]).

(b) - (d) (No change.)

(e) Transfer of Prescription Drug Order Information. Unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a Class E pharmacy may not refuse to transfer prescriptions to another pharmacy that [~~who~~] is making the transfer request on behalf of the patient.

(f) (No change.)

§291.105. Records.

(a) Maintenance of records.

(1) Every record required to be kept under this section shall be:

(A) kept by the pharmacy and be available, for at least two years from the date of such record, for inspecting and copying by the board or its representative, and other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(2) (No change.)

(b) (No change.)

~~[(c) Confidentiality.]~~

~~[(1) A Class E pharmacy shall provide adequate security of prescription drug order and patient medication records to prevent indiscriminate or unauthorized access to confidential health information. If prescription drug orders, requests for refill authorization, or other confidential health information are not transmitted directly between a pharmacy and a physician but are transmitted through a data communication device, confidential health information may not be accessed or maintained by the operator of the data communication device other than for legal purposes under federal and state law.]~~

~~[(2) Confidential records are privileged and may be released only to:]~~

~~[(A) the patient or the patient's agent;]~~

~~[(B) practitioners and other pharmacists if, in the pharmacist's professional judgment, the release is necessary to protect the patient's health and well-being;]~~

~~[(C) the board or to a person or another state or federal agency authorized by law to receive the confidential record;]~~

~~[(D) a law enforcement agency engaged in investigation of a suspected violation Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.);]~~

~~[(E) a person employed by a state agency that licenses a practitioner, if the person is performing the person's official duties; or]~~

~~[(F) an insurance carrier or third party payer authorized by a patient to receive such information.]~~

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES

22 TAC §§291.120, 291.121, 291.123, 291.125, 291.127, 291.129, 291.131, 291.133

The Texas State Board of Pharmacy proposes new §291.120, concerning General, §291.121, concerning Remote Pharmacy

Services, §291.123, concerning Central Prescription Drug or Medication Order Processing, §291.125, concerning Centralized Prescription Dispensing, §291.127, concerning Emergency Remote Pharmacy License, §291.129, concerning Satellite Pharmacy, §291.131, concerning Pharmacies Compounding Non-sterile Preparations, and §291.33, concerning Pharmacies Compounding Sterile Preparations.

New §291.120, if adopted, provides the purpose of the new subchapter. New §291.121, if adopted, contains the requirements for remote pharmacy services previously found in §291.20 which is proposed as a repealed rule published in this edition of the *Texas Register.* New §291.123, if adopted, provides the requirements for Central Prescription Drug Order or Medication Order Processing previously found in §291.38 which is proposed as a repealed rule published elsewhere in this edition of the *Texas Register.* New §291.125, if adopted, provides the requirements for Centralized Prescription Dispensing previously found in §291.37 which is proposed as a repealed rule published elsewhere in this edition of the *Texas Register.* New §291.127, if adopted, provides the requirements for Emergency Remote Pharmacy License previously found in §291.13 which is proposed as a repealed rule published elsewhere in this edition of the *Texas Register.* New §§291.121, 291.123, 291.125, and 291.127 are being moved from other sections in Chapter 291 to better organize the subchapters, contain formatting and grammar corrections, and require pharmacies to provide the board or its representative with records in electronic format, if the records are maintained in an electronic format.

New §291.129, if adopted, provides new rules for a new class of pharmacy regarding the provision of pharmacy services by a satellite pharmacy owned by a Class A or Class C pharmacy, in a location that is not at the same location as a Class A or Class C pharmacy. New §291.131, if adopted, will outline operating standards for pharmacies that compound non-sterile preparations, implement the recommendations of the TSBP appointed Task Force on Compounding (Task Force), and incorporate many of the provisions included in the United States Pharmacopeia (USP) General Chapter 795 (Pharmaceutical Compounding (Non-sterile Preparations) in accordance with S.B. 492 passed during the 79th Regular Session of the Texas Legislature regarding compounding. New §291.133, if adopted, will outline operating standards for pharmacies that compound sterile preparations, implement the recommendations of the TSBP appointed Task Force on Compounding (Task Force), and incorporate provisions included in the United States Pharmacopeia (USP) General Chapter 797 (Pharmaceutical Compounding (Sterile Preparations) in accordance with S.B. 492 passed during the 79th Regular Session of the Texas Legislature regarding compounding.

The TSBP established the Task Force in September 2005. The Task Force was composed of representatives from the pharmacy community appointed by the three major pharmacy associations in Texas and pharmacists primarily involved in compounding. The Task Force was established to review the current standards of practice for pharmacy compounding and was charged with: (1) reviewing current federal and state requirements for pharmacy compounding; (2) reviewing S.B. 492 passed by the 79th Texas Legislature with regard to pharmacy compounding; and (3) making recommendations to the Board of Pharmacy regarding standards for pharmacy compounding in Texas that provide necessary compounded medications while protecting the health, safety, and welfare of the public. The Task Force met three times and presented its recommendations to the Board at the October 31, 2006 meeting. The Task Force recommended incorporating many of the proposed revisions to USP General Chapter 797 (Pharmaceutical Compounding - Sterile Preparations) into the rules. In November 2006, the Board voted to propose the rules recommended by the Task Force. The proposed rules were published in the December 16, 2006, issue of the *Texas Register.* A public hearing was held on February 13, 2007. At the February Board meeting, the Board voted to withdraw the proposed rules based on comments received and directed staff to reconvene the Task Force. The Board directed staff to draft rules that only incorporated current USP 797 requirements. After reviewing the revised draft of rules at the May 2007 meeting, the Board voted to publish the draft rules as proposed rules. In accordance with S.B. 492, the Task Force recommended changes to the rules to allow (1) pharmacies to compound preparations for "office use" by a practitioner or for use by veterinarians as specified in §563.054 of the Texas Pharmacy Act; (2) Class A pharmacies to compound preparations for a Class C pharmacy; and (3) Class C pharmacies to compound preparations to other Class C pharmacies under common ownership.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state government as a result of enforcing or administering the rule. There are no anticipated fiscal implications for local government.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the rule will be the establishment of rules for the operation of satellite pharmacies and the establishment of standards for the safe compounding of non-sterile and sterile preparations by pharmacies. Ms. Dodson has also determined that, for each year of the first five-year period the rule will be in effect, an economic cost may exist for entities/persons required to comply with the rule as described below.

There might be an adverse economic effect on micro, small, and large businesses or to other entities/persons who are required to comply with the rules for pharmacies compounding sterile preparations. Based on the significant variances in pharmacies' physical structure and layout, it is difficult for TSBP to determine the actual cost to businesses required to comply with this rule. These costs would involve bringing the sterile compounding area of pharmacies into compliance with the new provisions of the rules and in establishing media fill test procedures. TSBP cannot precisely determine the number of pharmacies affected because TSBP records do not provide information about the details of the pharmacies' compounding operations. In addition, TSBP is unable to reduce these costs because to do so would compromise the purposes of this rule which is intended to protect the health and safety of the public. In order to comply with the library requirements, pharmacies compounding sterile preparations that do not already maintain a copy of the USP would incur a minimum cost of $690. In order to comply with the library requirements, pharmacies compounding non-sterile preparations that do not already maintain a copy of USP Chapter 795 would incur a minimum cost of $225.00.

Examples of new requirements under the rules are: (1) low- and medium-risk preparations must be prepared in a designated room for compounding; (2) when preparing high-risk preparations, the primary engineering control must be located in a buffer room that provides a physical separation, through the use of walls, doors and pass through and has a minimum differential positive pressure of 0.02 to 0.05 inches water column; (3) the

pharmacy must establish medial fill test procedures for low, medium and high-risk preparations; and (4) the pharmacy must establish a quality control and quality assurance program that meets the requirements of Chapter 797 of the USP. The actual dollar amount for bringing the pharmacy into compliance may vary greatly between pharmacies and could range from one hundred to several tens of thousand dollars. The majority of pharmacies have less than 100 employees, such that the cost per employee would result in an amount between one dollar per employee to several thousand dollars.

A public hearing to receive comments on the proposed §291.131 and §291.133 will be held at 9:00 a.m. on Tuesday, August 7, 2007, at the Health Professions Council Board Room, 333 Guadalupe Street, Tower II, Room 2-225, Austin, Texas 78701. Persons planning to present comments to the Board are asked to provide a written copy of their comments prior to the hearing or bring 20 copies to the hearing. Written comments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, 333 Guadalupe Street, Suite 3-600, Austin, Texas, 78701, FAX: (512) 305-8082, E-mail: allison.benz@tsbp.state.tx.us. Comments must be received by 5:00 p.m., July 30, 2007.

The new rules are proposed under §§551.002, 551.003, 554.001, 554.051, 560.053 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §551.003(9) as authorizing the agency to adopt rules concerning the compounding of prescriptions. The Board interprets §551.003(33) as authorizing the agency to adopt rules concerning the practice of pharmacy. The Board interprets §554.001(a) as authorizing the agency to adopt rules to administer and enforce the Act and rules adopted under the Act as well as enforce other laws relating to the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act. The Board interprets §554.051(b) as authorizing the agency to adopt rules concerning the operation of a licensed pharmacy located in this state applicable to a pharmacy licensed by the board that is located in another state, if the board determines the rule is necessary to protect the health and welfare of the citizens of this state. The Board interprets §560.053 as authorizing the agency to adopt rules establishing additional pharmacy classifications.

The statutes affected: Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.120. General.

(a) Purpose. This subchapter applies to all classes of pharmacies except as otherwise noted.

(b) Definitions.

(1) The Texas Pharmacy Act or Act--Subtitle J, other than Chapter 567, Occupations Code, as amended.

(2) Board--The Texas State Board of Pharmacy.

§291.121. Remote Pharmacy Services.

(a) Remote pharmacy services using automated pharmacy systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an automated pharmacy system as outlined in §562.109 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act.

(A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and maintains related transaction information.

(B) Remote site--A facility not located at the same location as a Class A or Class C pharmacy, at which remote pharmacy services are provided using an automated pharmacy dispensing system.

(C) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container, or quantities of unit dosed drugs, into another cartridge or container for dispensing by a pharmacist using an automated pharmacy system.

(D) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.

(E) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, in remote sites.

(F) Unit dose--An amount of a drug packaged in a dosage form ready for administration to a particular patient, by the prescribed route at the prescribed time, and properly labeled with name, strength, and expiration date of the drug.

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using an automated pharmacy system to a jail or prison operated by or for the State of Texas, a jail or prison operated by local government or a healthcare facility regulated under Chapter 142, 242, 247, or 252, Health and Safety Code, provided drugs are administered by a licensed healthcare professional working in the jail, prison, or healthcare facility.

(B) A provider pharmacy may only provide remote pharmacy services using an automated pharmacy system to inpatients of the remote site.

(C) A provider pharmacy may provide remote pharmacy services at more than one remote site.

(D) Before providing remote pharmacy services, the automated pharmacy system at the remote site must be tested by the provider pharmacy and found to dispense accurately. The provider pharmacy shall make the results of such testing available to the board upon request.

(E) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel, Operational Standards, and Records for Class A (Community) Pharmacies) and this section.

(F) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the automated pharmacy system located at the remote site including supervision of the automated pharmacy system and compliance with this section.

(G) A pharmacist from the provider pharmacy shall be accessible at all times to respond to patient's or other health professionals' questions and needs pertaining to drugs dispensed through the use

of the automated pharmacy system. Such access may be through a 24 hour pager service or telephone which is answered 24 hours a day.

(4) Operational standards.

(A) Application for permission to provide pharmacy services using an automated pharmacy system.

(i) A Class A or Class C Pharmacy shall make application to the board to provide remote pharmacy services using an automated pharmacy system. The application shall contain an affidavit with the notarized signatures of the pharmacist-in-charge, and the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, chief operating officer, owner, chief executive officer), and include the following:

(I) the name, address, and license number of the provider pharmacy;

(II) name and address of the facility where the remote pharmacy services will be provided;

(III) a statement indicating that the provider pharmacy and the facility have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations; and

(IV) documentation that the automated pharmacy system is located where medications are administered by license healthcare professionals and is:

(-a-) a facility regulated under Chapter 142, 242, 247, or 252, Health and Safety Code; or

(-b-) a jail or prison, operated by the State of Texas or local government.

(ii) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license. The renewal petition shall contain the documentation required in clause (i) of this subparagraph except the notarized signature of the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, chief operating officer, owner, chief executive officer) is not required.

(iii) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the remote site.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a change of location, discontinuance of service, or closure of:

(I) a remote site where an automated pharmacy system is operated by the pharmacy; or

(II) a remote pharmacy service at a remote site.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site if controlled substances are maintained within an automated pharmacy system at the facility.

(C) Environment/Security.

(i) A provider pharmacy shall only store drugs at a remote site within an automated pharmacy system which is locked by key, combination or other mechanical or electronic means so as to prohibit access by unauthorized personnel.

(ii) An automated pharmacy system shall be under the continuous supervision of a provider pharmacy pharmacist. To qualify as continuous supervision, the pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is supervised electronically by a pharmacist.

(iii) Automated pharmacy systems shall have adequate security and procedures to:

(I) comply with federal and state laws and regulations; and

(II) maintain patient confidentiality.

(iv) Access to the automated pharmacy system shall be limited to pharmacists or personnel who:

(I) are designated in writing by the pharmacist-in-charge; and

(II) have completed documented training concerning their duties associated with the automated pharmacy system.

(v) Drugs shall be stored in compliance with the provisions of §291.33(f) of this title including the requirements for temperature, proper storage containers, and handling of outdated drugs.

(D) Prescription dispensing and delivery.

(i) Drugs shall only be dispensed at a remote site through an automated pharmacy system after receipt of an original prescription drug order by a pharmacist at the provider pharmacy in a manner authorized by §291.34(b) of this title.

(ii) A pharmacist at the provider pharmacy shall control all operations of the automated pharmacy system and approve the release of the initial dose of a prescription drug order. Subsequent doses from an approved prescription drug order may be removed from the automated medication system after this initial approval. Any change made in the prescription drug order shall require a new approval by a pharmacist to release the drug.

(iii) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified in §291.33(c) of this title prior to releasing a prescription drug order to the automated pharmacy system.

(iv) Drugs dispensed by the provider pharmacy through an automated pharmacy system shall comply with the labeling or labeling alternatives specified in §291.33(c) of this title.

(v) An automated pharmacy system used to meet the emergency medication needs for residents of a remote site must comply with the requirements for emergency medication kits in subsection (b) of this section.

(E) Drugs.

(i) Drugs for use in an automated pharmacy system shall be packaged in the original manufacturer's container or be prepackaged in the provider pharmacy and labeled in compliance with the board's prepackaging requirements for the class of pharmacy.

(ii) Drugs dispensed from the automated pharmacy system may be returned to the pharmacy for reuse provided the drugs are in sealed, tamper evident packaging which has not been opened.

(F) Stocking an automated pharmacy system.

(i) Stocking of drugs in an automated pharmacy system shall be completed by a pharmacist, pharmacy technician, or pharmacy technician trainee under the direct supervision of a pharmacist, except as provided in clause (ii) of this subparagraph.

(ii) If the automated pharmacy system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers shall occur at the provider pharmacy unless provided by an FDA approved repackager. The prepackaged cartridges or containers may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(I) a pharmacist verifies the cartridge or container has been properly filled and labeled;

(II) the individual cartridges or containers are transported to the remote site in a secure, tamper-evident container; and

(III) the automated pharmacy system uses barcoding, microchip, or other technologies to ensure that the containers are accurately loaded in the automated pharmacy system.

(iii) All drugs to be stocked in the automated pharmacy system shall be delivered to the remote site by the provider pharmacy.

(G) Quality assurance program. A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to a written program for quality assurance of the automated pharmacy system which:

(i) requires continuous supervision of the automated pharmacy system; and

(ii) establishes mechanisms and procedures to routinely test the accuracy of the automated pharmacy system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(H) Policies and procedures of operation.

(i) A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) a current list of the name and address of the pharmacist-in-charge and personnel designated by the pharmacist-in-charge to have access to the drugs stored in the automated pharmacy system;

(II) duties which may only be performed by a pharmacist;

(III) a copy of the portion of the written contract or agreement between the pharmacy and the facility which outlines the services to be provided and the responsibilities and accountabilities of each party relating to the operation of the automated pharmacy system in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

(IV) date of last review/revision of the policy and procedure manual; and

(V) policies and procedures for:

(-a-) security;
(-b-) operation of the automated pharmacy system;
(-c-) preventative maintenance of the automated pharmacy system;
(-d-) sanitation;
(-e-) storage of drugs;
(-f-) dispensing;
(-g-) supervision;
(-h-) drug procurement;
(-i-) receiving of drugs;
(-j-) delivery of drugs; and
(-k-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an automated pharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of the automated pharmacy system to dispense prescription drugs. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated pharmacy system is experiencing downtime;

(II) procedures for response when an automated pharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(ii) The provider pharmacy shall maintain original prescription drug orders for drugs dispensed from an automated pharmacy system in compliance with §291.34(b) of this title.

(iii) if prescription drug records are maintained in a data processing system, the system shall have a workable (electronic) data retention system which can produce a separate audit trail of drug usage by the provider pharmacy and each remote site for the preceding two years as specified in §291.34(e) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Records of dispensing. Dispensing records for a prescription drug order shall be maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(D) Transaction information.

(i) The automated pharmacy system shall electronically record all transactions involving drugs stored in, removed, or dispensed from the system.

(ii) Records of dispensing from an automated pharmacy system for a patient shall be maintained by the providing pharmacy and include the:

(I) identity of the system accessed;

(II) identification of the individual accessing the system;

(III) date of transaction;

(IV) name, strength, dosage form, and quantity of drug accessed; and

(V) name of the patient for whom the drug was accessed.

(iii) Records of stocking or removal from an automated pharmacy system shall be maintained by the pharmacy and include the:

(I) date;

(II) name, strength, dosage form, and quantity of drug stocked or removed;

(III) name, initials, or identification code of the person stocking or removing drugs from the system;

(IV) name, initials, or identification code of the pharmacist who checks and verifies that the system has been accurately filled;

(E) Patient medication records. Patient medication records shall be created and maintained by the provider pharmacy in the manner required by §291.34(c) of this title.

(F) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the records of the provider pharmacy and from any other remote site's records; and

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title (relating to Inventory Requirements for All Classes of Pharmacies), that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs of the provider pharmacy.

(b) Remote pharmacy services using emergency medication kits.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an emergency medication kit as outlined in §562.108 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and maintains related transaction information.

(B) Emergency medication kits--Controlled substances and dangerous drugs maintained by a community pharmacy (Class A), an institutional pharmacy (Class C) at an institution licensed under Chapter 242 or 252, Health and Safety Code, a non-resident (Class E) pharmacy located not more than 20 miles from an institution licensed under Chapter 242 or 252, Health and Safety Code, or a United States Department of Veterans Affairs pharmacy or another federally operated pharmacy at an institution that is licensed under Chapter 242, Health and Safety Code, and is a veterans home, as defined by Section 164.002, Natural Resources Code, to meet the emergency medication needs of a resident at that institution.

(C) Remote site--A facility not located at the same location as a Class A, Class C, Class E pharmacy or a United States Department of Affairs pharmacy or another federally operated pharmacy, at which remote pharmacy services are provided using an emergency medication kit.

(D) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container, or quantities of unit dosed drugs, into another cartridge or container for dispensing by a pharmacist using an emergency medication kit.

(E) Provider pharmacy--The community pharmacy (Class A), the institutional pharmacy (Class C), the non-resident (Class E) pharmacy located not more than 20 miles from an institution licensed under Chapter 242 or 252, Health and Safety Code, or the United States Department of Veterans Affairs pharmacy or another federally operated pharmacy providing remote pharmacy services.

(F) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, in remote sites.

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using an emergency medication kit to an institution regulated under Chapter 242, or 252, Health and Safety Code.

(B) A provider pharmacy may provide remote pharmacy services at more than one remote site.

(C) A provider pharmacy shall not place an emergency medication kit in a remote site which already has a kit from another provider pharmacy.

(D) A provider pharmacy which is licensed as an institutional (Class C) or a non-resident (Class E) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this section.

(E) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the emergency medication kit located at the remote site including supervision of the emergency medication kit and compliance with this section.

(4) Operational standards.

(A) Application for permission to provide pharmacy services using an emergency medication kit.

(i) A Class A, Class C, or Class E Pharmacy shall make application to the board to provide remote pharmacy services using an emergency medication kit. The application shall contain an affidavit with the notarized signatures of the pharmacist-in-charge, and the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief operating officer), and include the following:

(I) the name, address, and license number of the provider pharmacy;

(II) name and address of the healthcare facility where the remote pharmacy services will be provided;

(III) a statement indicating that the provider pharmacy and the healthcare facility have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations;

(IV) documentation that the emergency medication kit is located in a facility regulated under Chapter 242, or 252, Health and Safety Code; and

(V) documentation that the emergency kit is located in a facility that is not more than 20 miles from the Class E pharmacy providing the emergency kit.

(ii) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license. The renewal petition shall contain the documentation required in clause (i) of this subparagraph except the notarized signature of the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief operating officer) is not required.

(iii) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the remote site.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a change of location, discontinuance of service, or closure of:

(I) a remote site where an emergency medication kit is operated by the pharmacy; or

(II) a remote pharmacy service at a remote site.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site if controlled substances are maintained within an emergency medication kit at the facility.

(C) Environment/Security.

(i) Emergency medication kits shall have adequate security and procedures to:

(I) prohibit unauthorized access;

(II) comply with federal and state laws and regulations; and

(III) maintain patient confidentiality.

(ii) Access to the emergency medication kit shall be limited to pharmacists and licensed healthcare personnel employed by the facility.

(iii) Drugs shall be stored in compliance with the provisions of §291.33(f) of this title including the requirements for temperature, proper storage containers, and handling outdated drugs.

(D) Prescription dispensing and delivery.

(i) Drugs in the emergency medication kit shall be accessed for administration to meet the emergency medication needs of a resident of the remote site pursuant to an order from a practitioner. The prescription drug order for the drugs used from the emergency medication kit shall be forwarded to the provider pharmacy in a manner authorized by §291.34(b) of this title.

(ii) The remote site shall notify the provider pharmacy of each entry into an emergency medication kit. Such notification shall meet the requirements of paragraph (5)(D)(ii) of this subsection.

(E) Drugs.

(i) The contents of an emergency medication kit:

(I) may consist of dangerous drugs and controlled substances; and

(II) shall be determined by the consultant pharmacist, pharmacist-in-charge of the provider pharmacy, medical director, and the director of nurses and limited to those drugs necessary to meet the resident's emergency medication needs. For the purpose of this subsection, this shall mean a situation in which a drug cannot be supplied by a pharmacy within a reasonable time period.

(ii) When deciding on the drugs to be placed in the emergency medication kit, the consultant pharmacist, pharmacist-in-charge of the provider pharmacy, medical director, and the director of nurses must determine, select, and record a prudent number of drugs for potential emergency incidents based on:

(I) clinical criteria applicable to each facility's demographics;

(II) the facility's census; and

(III) the facility's healthcare environment.

(iii) A current list of the drugs stored in each remote site's emergency medication kit shall be maintained by the provider pharmacy and a copy kept with the emergency medication kit.

(iv) An automated pharmacy system may be used as an emergency medication kit provided the system limits emergency access to only those drugs approved for the emergency medication kit.

(v) Drugs for use in an emergency medication kit shall be packaged in the original manufacturer's container or prepackaged in the provider pharmacy and labeled in compliance with the board's prepackaging requirements for the class of pharmacy.

(F) Stocking emergency medication kits.

(i) Stocking of drugs in an emergency medication kit shall be completed at the provider pharmacy or remote site by a pharmacist, pharmacy technician, or pharmacy technician trainee under the direct supervision of a pharmacist, except as provided in clause (ii) of this subparagraph.

(ii) If the emergency medication kit is an automated pharmacy system which uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers shall occur at the provider pharmacy unless provided by and FDA approved repackager. The prepackaged cartridges or containers may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(I) a pharmacist verifies the cartridge or container has been properly filled and labeled;

(II) the individual cartridges or containers are transported to the remote site in a secure, tamper-evident container; and

(III) the automated pharmacy system uses barcoding, microchip, or other technologies to ensure that the containers are accurately loaded in the automated pharmacy system.

(iii) All drugs to be stocked in the emergency medication kit shall be delivered to the remote site by the provider pharmacy.

(G) Policies and procedures of operation.

(i) A provider pharmacy that provides pharmacy services through an emergency medication kit at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) duties which may only be performed by a pharmacist;

(II) a copy of the written contract or agreement between the pharmacy and the facility which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

(III) date of last review/revision of the policy and procedure manual; and

(IV) policies and procedures for:

(-a-) security;

(-b-) operation of the emergency medication kit;

(-c-) preventative maintenance of the automated pharmacy system if the emergency medication kit is an automated pharmacy system;

(-d-) sanitation;

(-e-) storage of drugs;

(-f-) dispensing;

(-g-) supervision;

(-h-) drug procurement;

(-i-) receiving of drugs;

(-j-) delivery of drugs; and

(-k-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through an emergency medication kit at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an emergency medication kit which is an automated pharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of the automated pharmacy system to provide emergency medications. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated pharmacy system is experiencing downtime;

(II) procedures for response when an automated pharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(ii) The provider pharmacy shall maintain original prescription drug orders for drugs dispensed from an emergency medication kit in compliance with §291.34(b) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Records of dispensing. Dispensing records for a prescription drug order shall be maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(D) Transaction information.

(i) A prescription drug order shall be maintained by the provider pharmacy as the record of removal of a drug from an emergency medication kit for administration to a patient.

(ii) The remote site shall notify the provider pharmacy electronically or in writing of each entry into an emergency medication kit. Such notification may be included on the prescription drug order or a separate document and shall include the name, strength, and quantity of the drug removed, the time of removal, and the name of the person removing the drug.

(iii) A separate record of stocking, removal, or dispensing for administration from an emergency medication kit shall be maintained by the pharmacy and include the:

(I) date;

(II) name, strength, dosage form, and quantity of drug stocked, removed, or dispensed for administration;

(III) name, initials, or identification code of the person stocking, removing, or dispensing for administration, drugs from the system;

(IV) name, initials, or identification code of the pharmacist who checks and verifies that the system has been accurately filled; and

(V) unique prescription number assigned to the prescription drug order when the drug is administered to the patient.

(E) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the records of the provider pharmacy and from any other remote site's records; and

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title, that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs of the provider pharmacy.

(c) Remote pharmacy services using telepharmacy systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a healthcare facility that is not at the same location as a Class A or Class C pharmacy through a telepharmacy system as outlined in §562.110 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(A) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container into a prescription container for dispensing by a pharmacist to the ultimate consumer.

(B) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.

(C) Remote site--a facility not located at the same location as a Class A or Class C pharmacy, at which remote pharmacy services are provided using a telepharmacy dispensing system.

(D) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, drug regimen review, and patient counseling, at a remote site.

(E) Still image capture--A specific image captured electronically from a video or other image capture device.

(F) Store and forward--A video or still image record which is saved electronically for future review.

(G) Telepharmacy system--A system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method which shall include the use of the following types of technology:

(i) audio and video;

(ii) still image capture; and

(iii) store and forward.

(H) Unit-of-use--A sufficient quantity of a drug for one normal course of therapy as determined by the pharmacist-in-charge and the prescribing practitioner(s) at the healthcare facility.

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using a telepharmacy system to:

(i) a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended;

(ii) a health center as defined by 42 U.S.C. Section 254b, as amended; or

(iii) healthcare facility located in a medically underserved area as defined by state or federal law.

(B) A provider pharmacy may not provide remote pharmacy services if a Class A (Community) or Class C (Institutional) pharmacy that dispenses prescription drug orders to out-patients is located in the same community. For the purposes of this subsection a community is defined as:

(i) the census tract in which the remote site is located, if the remote site is located in a Metropolitan Statistical Area (MSA) as defined by the United States Census Bureau in the most recent U.S. Census; or

(ii) within 10 miles of the remote site, if the remote site is not located in a MSA.

(C) The provider pharmacy shall have sufficient pharmacists on duty such that each pharmacist may supervise no more than three remote sites that are simultaneously open to provide services. An exception to the supervision limit may be granted by the board in situations where the provider has documented a need for a pharmacist to supervise additional remote sites and has demonstrated that appropriate safeguards are in place to assure proper supervision of each remote site.

(D) Before providing remote pharmacy service, the telepharmacy system at the off-site facility must be tested by the provider pharmacy and found to operate properly. The provider pharmacy shall make the results of such testing available to the board upon request.

(E) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this section.

(F) The pharmacist-in-charge of the provider pharmacy is responsible for all operations at the remote site including supervision of the telepharmacy system and compliance with this section.

(4) Operational standards.

(A) Application to provide pharmacy services using a telepharmacy system.

(i) A Class A or class C Pharmacy shall make application to the board to provide remote pharmacy services using a telepharmacy system. The application shall contain an affidavit with the notarized signatures of pharmacist-in-charge, and the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief operating officer), and include the following:

(I) the name, address, and license number of the provider pharmacy;

(II) name and address of the healthcare facility where the remote pharmacy services will be provided;

(III) a statement indicating that the provider pharmacy and the healthcare facility have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations;

(IV) documentation that the healthcare facility is:

(-a-) a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended;

(-b-) a health center as defined by 42 U.S.C. Section 254b, as amended; or

(-c-) located in a medically underserved area as defined by state or federal law; and

(V) documentation that a Class A (Community) or Class C (Institutional) Pharmacy that dispenses prescriptions drug

orders to out-patients is not located within the community, as defined in paragraph (3)(B) of this subsection, where the remote site is located.

(ii) Such application shall be resubmitted every two years in conjunction with the renewal of the provider pharmacy's license. The renewal application shall contain the documentation required in clause (i) of this subparagraph except the notarized signature of the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief operating officer) is not required.

(iii) On approval of the application, the provider pharmacy will be sent a registration certificate, which must be displayed at the remote site.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a change of location, discontinuance of service, or closure of:

(I) a remote site where a telepharmacy system is operated by the pharmacy; or

(II) a remote pharmacy service at a remote site.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site, if controlled substances are maintained.

(C) Environment/Security.

(i) A remote site shall be under the continuous supervision of a provider pharmacy pharmacist at all times the site is open to provide pharmacy services. To qualify as continuous supervision, the pharmacist is not required to be physically present at the remote site and shall supervise electronically through the use of the following types of technology:

(I) audio and video;

(II) still image capture; and

(III) store and forward.

(ii) Drugs shall be stored in compliance with the provisions of §291.33(f) of this title including the requirements for temperature, proper containers, and handling of outdated drugs.

(iii) Drugs for use in the telepharmacy system shall be stored in an area that is:

(I) separate from any other drugs used by the healthcare facility; and

(II) locked by key, combination or other mechanical or electronic means, so as to prohibit access by unauthorized personnel.

(iv) Access to the area where drugs are stored at the remote site and operation of the telepharmacy system shall be limited to pharmacists employed by the provider pharmacy or personnel who:

(I) are licensed healthcare providers pharmacy technicians or pharmacy technician trainees;

(II) are designated in writing by the pharmacist-in-charge; and

(III) have completed documented training concerning their duties associated with the telepharmacy pharmacy system.

(v) Remote sites shall have adequate security and procedures to:

(I) comply with federal and state laws and regulations; and

(II) maintain patient confidentiality.

(vi) The provider pharmacy shall have procedures that specify that drugs may only be delivered to the remote site by the provider pharmacy and shall:

(I) be shipped in a sealed container with a list of drugs delivered;

(II) signed for on receipt by an employee of the healthcare facility;

(III) be quarantined in a locked area, if personnel designated to receive the drugs by the pharmacist-in-charge is not available; and

(IV) be checked by personnel designated by the pharmacist-in-charge to verify that drugs sent by the provider pharmacy were actually received. The designated person who checks the order shall document the verification by signing and dating the list of drugs delivered.

(D) Prescription dispensing and delivery.

(i) Drugs shall only be dispensed at the remote site through a telepharmacy system after receipt of an original prescription drug order by a pharmacist at the provider pharmacy in the manner authorized by §291.34(b) of this title.

(ii) Drugs may be dispensed by the provider pharmacy through a telepharmacy system at a remote site only in unit-of-use containers that are:

(I) prepackaged in suitable containers at the provider pharmacy and appropriately labeled as specified in §291.33(c)(4) of this title; or

(II) in original manufacturer's containers.

(iii) The following duties shall be performed only by a pharmacist at the provider pharmacy:

(I) receiving an oral prescription drug order;

(II) interpret the prescription drug order;

(III) verify the accuracy of prescription data entry;

(IV) select the drug product;

(V) interpret the patient's medication record and conduct a drug regimen review as specified in clause (iv) of this subparagraph;

(VI) authorize the telepharmacy system to print a prescription label at the remote site as specified in clause (v) of this subparagraph;

(VII) perform the final check of the dispensed prescription as specified in clause (vi) of this subparagraph to ensure that the prescription drug order has been dispensed accurately as prescribed;

(VIII) counsel the patient as specified clause (vii) of this subparagraph.

(iv) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified in §291.33(c) of this title prior to delivery of the dispensed prescription to the patient or patient's agent.

(v) The dispensed prescription shall be labeled at the remote site with the information specified in §291.33(c) of this title except that:

(I) the label shall contain both the name, address, and phone number of the provider pharmacy and the name and address of the remote site; and

(II) the unique identification number of the prescription on the label shall in some manner identify the remote site which dispensed the prescription using a telepharmacy system.

(vi) A pharmacist at the provider pharmacy shall perform the final check of the dispensed prescription before delivery to the patient to ensure that the prescription has been dispensed accurately as prescribed. This final check shall be accomplished through a visual check using electronic methods.

(vii) A pharmacist at the provider pharmacy shall counsel the patient or patient's agent as specified in §291.33(c) of this title. This counseling may be performed using electronic methods. Non-pharmacist personnel may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(viii) If the remote site has direct access to the provider pharmacy's data processing system, only a pharmacist, pharmacy technician, or pharmacy technician trainee may enter prescription information into the data processing system. The original prescription shall be sent to the provider pharmacy and a pharmacist shall verify the accuracy of the data entry.

(ix) Drugs which require reconstitution through the addition of a specified amount of water may be dispensed by the remote site only if a pharmacy technician, pharmacy technician trainee, or licensed healthcare provider reconstitutes the product.

(E) Quality assurance program. A pharmacy that provides pharmacy services through a telepharmacy system at a remote site shall operate according to a written program for quality assurance of the telepharmacy system which:

(i) requires continuous supervision of the telepharmacy system at all times the site is open to provide pharmacy services; and

(ii) establishes mechanisms and procedures to routinely test the operation of the telepharmacy system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(F) Policies and procedures.

(i) A pharmacy that provides pharmacy services through a telepharmacy system at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) a current list of the name and address of the pharmacist-in-charge and personnel designated by the pharmacist-in-charge to have:

(-a-) have access to the area where drugs are stored at the remote site; and

(-b-) operate the telepharmacy system;

(II) duties which may only be performed by a pharmacist;

(III) a copy of the written contact or agreement between the provider pharmacy and the healthcare facility which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations;

(IV) date of last review/revision of policy and procedure manual; and

(V) policies and procedures for:

(-a-) security;
(-b-) operation of the telepharmacy system;
(-c-) sanitation;
(-d-) storage of drugs;
(-e-) dispensing;
(-f-) supervision;
(-g-) drug and/or device procurement;
(-h-) receiving of drugs and/or devices;
(-i-) delivery of drugs and/or devices; and
(-j-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through a telepharmacy system at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services through a telepharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of a pharmacist to electronically supervise the telepharmacy system and the dispensing of prescription drugs at the remote site. The written plan for recovery shall include:

(I) a statement that prescription drugs shall not be dispensed at the remote site, if a pharmacists is not able to electronically supervise the telepharmacy system and the dispensing of prescription drugs;

(II) procedures for response when a telepharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(ii) The provider pharmacy shall maintain original prescription drug orders for medications dispensed from a remote site using a telepharmacy system in the manner required by §291.34(b) of this title.

(iii) If prescription drug records are maintained in a data processing system, the system shall have a workable (electronic) data retention system which can produce a separate audit trail of drug usage by the provider pharmacy and by each remote site for the preceding two years as specified in §291.34(e) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Patient medication records. Patient medication records shall be created and maintained at the provider pharmacy in the manner required by §291.34(c) of this title.

(D) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the records of the provider pharmacy and from any other remote site's records;

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title, that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title. A provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs at the provider pharmacy.

§291.123. Central Prescription Drug or Medication Order Processing.

(a) Purpose.

(1) The purpose of this section is to provide standards for centralized prescription drug or medication order processing by a Class A (Community), Class C (Institutional), or Class E (Non-Resident) pharmacy.

(2) Any facility established for the purpose of processing prescription drug or medication drug orders shall be licensed as a Class A, Class C, or Class E pharmacy under the Act. However, nothing in this subsection shall prohibit an individual pharmacist employee who is licensed in Texas from remotely accessing the pharmacy's electronic data base from outside the pharmacy in order to process prescription or medication drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act. Centralized prescription drug or medication order processing--the processing of a prescription drug or medication orders by a Class A, Class C, or Class E pharmacy on behalf of another pharmacy, a health care provider, or a payor. Centralized prescription drug or medication order processing does not include the dispensing of a prescription drug order but includes any of the following:

(1) receiving, interpreting, or clarifying prescription drug or medication drug orders;

(2) data entering and transferring of prescription drug or medication order information;

(3) performing drug regimen review;

(4) obtaining refill and substitution authorizations;

(5) interpreting clinical data for prior authorization for dispensing;

(6) performing therapeutic interventions; and

(7) providing drug information concerning a patient's prescription.

(c) Operational Standards.

(1) General requirements.

(A) A Class A, Class C, or Class E Pharmacy may outsource prescription drug or medication order processing to another Class A, Class C, or Class E pharmacy provided the pharmacies:

(i) have:

(I) the same owner; or

(II) entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations; and

(ii) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a non-dispensing function.

(B) A pharmacy that performs centralized prescription drug or medication order processing shall comply with the provisions applicable to the class of pharmacy contained in either §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational Standards, Records, and Official Prescription Requirements in Class A (Community) Pharmacies), or §§291.72 - 291.75 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class C (Institutional) Pharmacy), or §§291.102 - 291.105 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class E (Non-Resident) Pharmacy) to the extent applicable for the specific processing activity and this section including:

(i) duties which must be performed by a pharmacist; and

(ii) supervision requirements for pharmacy technicians and pharmacy technician trainees.

(2) Notifications to patients.

(A) A pharmacy that outsources prescription drug or medication order processing to another pharmacy shall prior to outsourcing their prescription:

(i) notify patients that prescription processing may be outsourced to another pharmacy; and

(ii) give the name of that pharmacy; or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may process the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.

(B) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., hospitals or nursing homes).

(3) Policy and Procedures. A policy and procedure manual as it relates to central processing shall be maintained at all pharmacies involved in central processing and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

(A) outline the responsibilities of each of the pharmacies;

(B) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription drug or medication order processing; and

(C) include policies and procedures for:

(i) protecting the confidentiality and integrity of patient information;

(ii) maintenance of appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any processing;

(iii) complying with federal and state laws and regulations;

(iv) operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(v) annually reviewing the written policies and procedures and documenting such review.

(d) Records. All pharmacies shall maintain appropriate records which identify, by prescription drug or medication order, the name(s), initials, or identification code(s) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs a processing function for a prescription drug or medication order. Such records may be maintained:

(1) separately by each pharmacy and pharmacist; or

(2) in a common electronic file as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy and pharmacist.

§291.125. Centralized Prescription Dispensing.

(a) Purpose. The purpose of this section is to provide standards for centralized prescription dispensing by a Class A (Community), Class C (Institutional) pharmacy, or Class E (Non-Resident) Pharmacy.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act. Centralized prescription dispensing--the dispensing or refilling of a prescription drug order by a Class A (Community), Class C (Institutional), or Class E (Non-Resident) pharmacy at the request of another Class A (Community), or Class C (Institutional) and the return of the dispensed prescriptions to the requesting pharmacy for delivery to the patient or patient's agent, or at the request of the requesting pharmacy, direct delivery to the patient.

(c) Operational standards.

(1) General requirements.

(A) A Class A (Community) or Class C (Institutional) pharmacy may outsource prescription drug order dispensing to another Class A (Community), Class C (Institutional), or Class E (Non-Resident) pharmacy provided the pharmacies:

(i) have:

(I) the same owner; or

(II) entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations; and

(ii) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to dispense or process a prescription drug order.

(B) The pharmacist-in-charge of the dispensing pharmacy shall ensure that:

(i) the pharmacy maintains and uses adequate storage or shipment containers and shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process; and

(ii) the dispensed prescriptions are shipped in containers which are sealed in a manner as to show evidence of opening or tampering.

(C) A Class A (Community) or Class C (Institutional) dispensing pharmacy shall comply with the provisions of §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational Standards, Records, and Official Prescription Requirements in Class A (Community) Pharmacies) and this section.

(D) A Class E (Non-Resident) dispensing pharmacy shall comply with §§291.101 - 291.105 of this title (relating to Purpose, Definitions, Personnel, Operational Standards, and Records in Class E (Non-Resident) Pharmacies) and this section.

(E) Pharmacies dispensing compounded non-sterile or sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations) and §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(2) Notifications to patients.

(A) A pharmacy that outsources prescription dispensing to another pharmacy shall:

(i) prior to outsourcing the prescription:

(I) notify patients that their prescription may be outsourced to another pharmacy; and

(II) give the name of that pharmacy or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may dispense the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy; and

(ii) if the prescription is delivered directly to the patient by the dispensing pharmacy and not returned to the requesting pharmacy, place on the prescription container or on a separate sheet delivered with the prescription container, in both English and Spanish, the local, and if applicable, the toll-free telephone number of the pharmacy and the statement: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."

(B) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., hospitals or nursing homes).

(3) Prescription Labeling. The dispensing pharmacy shall:

(A) place on the prescription label, the name and address or name and pharmacy license number of the pharmacy dispensing the prescription and the name and address of the pharmacy which receives the dispensed prescription;

(B) indicate in some manner which pharmacy dispensed the prescription (e.g., "Filled by ABC Pharmacy for XYZ Pharmacy"); and

(C) comply with all other labeling requirements in §291.33 of this title.

(4) Policies and Procedures. A policy and procedure manual as it relates to centralized dispensing shall be maintained at both pharmacies and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

(A) outline the responsibilities of each of the pharmacies;

(B) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription dispensing; and

(C) include policies and procedures for:

(i) notifying patients that their prescription may be outsourced to another pharmacy for centralized prescription dispensing and providing the name of that pharmacy;

(ii) protecting the confidentiality and integrity of patient information;

(iii) dispensing prescription drug orders when the filled order is not received or the patient comes in before the order is received;

(iv) complying with federal and state laws and regulations;

(v) operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(vi) annually reviewing the written policies and procedures and documenting such review.

(d) Records.

(1) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(A) the records maintained in the alternative system contain all of the information required on the manual record; and

(B) the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(2) Each pharmacy shall comply with all the laws and rules relating to the maintenance of records and be able to produce an audit trail showing all prescriptions dispensed by the pharmacy.

(3) The requesting pharmacy shall maintain records which indicate the date:

(A) the request for dispensing was transmitted to the dispensing pharmacy; and

(B) the dispensed prescription was received by the requesting pharmacy, including the method of delivery (e.g., private, common, or contract carrier) and the name of the person accepting delivery.

(4) The dispensing pharmacy shall maintain records which indicate:

(A) the date the prescription was shipped to the requesting pharmacy;

(B) the name and address where the prescription was shipped; and

(C) the method of delivery (e.g., private, common, or contract carrier).

§291.127. Emergency Remote Pharmacy License.

(a) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act.

(1) Emergency remote pharmacy--A pharmacy not located at the same Texas location as a home pharmacy at which pharmacy services are provided during an emergency situation.

(2) Emergency situation--An emergency caused by a natural or manmade disaster or any other exceptional situation that causes an extraordinary demand for pharmacy services.

(3) Home pharmacy--A currently licensed Class A (Community), Class C (Institutional), or Class D (Clinic) pharmacy that is providing emergency pharmacy services through an emergency remote pharmacy.

(b) Emergency remote pharmacy license. In an emergency situation, the board may grant a holder of a Class A (Community), Class C (Institutional), or Class D (Clinic) pharmacy license, the authority to operate a pharmacy and provide pharmacy services at an alternate location. The following is applicable for the emergency remote pharmacy.

(1) The emergency remote pharmacy will not be issued a separate pharmacy license, but shall operate under the license of the home pharmacy. To qualify for an emergency remote pharmacy license, the applicant must submit an application including the following information:

(A) license number, name, address, and phone number of the home pharmacy;

(B) name, address, and phone number of the emergency remote pharmacy;

(C) name and Texas pharmacist license number of the pharmacist-in-charge of the home pharmacy and of the pharmacist-in-charge of the emergency remote pharmacy; and

(D) any other information required by the board.

(2) The board will notify the home pharmacy of the approval of an emergency remote pharmacy license.

(3) The emergency remote pharmacy license shall be valid for a period as determined by the board not to exceed six months. The executive director of the board, in his/her discretion, may renew the remote license for an additional six months, if the emergency situation

still exists and the holder of the license shows good cause for emergency remote pharmacy to continue operation.

(4) The emergency remote pharmacy shall have a written contract or agreement with the home pharmacy which outlines the services to be provided and the responsibilities and accountabilities of the remote and home pharmacy in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations.

(5) The home pharmacy shall designate a pharmacist to serve as the pharmacist-in-charge of the emergency remote pharmacy.

(6) The emergency remote pharmacy shall comply with the rules for the class of pharmacy under which the home pharmacy is licensed. A Class A pharmacy shall comply with the rules under Subchapter B of this chapter titled Community Pharmacy (Class A). A Class C pharmacy shall comply with the rules under Subchapter D of this chapter titled Institutional Pharmacy (Class C). A Class D pharmacy shall comply with the rules under Subchapter E of this chapter titled Clinic Pharmacy (Class D).

(7) The records of services provided at the emergency remote pharmacy shall be:

(A) kept by the home pharmacy and be available, for at least two years from the date of provision of the service, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

§291.129. Satellite Pharmacy.

(a) Purpose. The purpose of this section is to create a new class of pharmacy for the provision of pharmacy services by a Class A or Class C pharmacy in a location that is not at the same location as a Class A or Class C pharmacy through a satellite pharmacy and to provide standards for the operation of this class of pharmacy established under §560.053 of the Texas Pharmacy Act.

(b) Definitions. The following words and terms, when used in the section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(1) Provider pharmacy--The Class A or Class C pharmacy providing satellite pharmacy services.

(2) Satellite pharmacy--A facility not located at the same location as a Class A or Class C pharmacy at which satellite pharmacy services are provided.

(3) Satellite pharmacy services--The provision of pharmacy services, including the storage and delivery of prescription drugs, in an alternate location.

(c) General requirements.

(1) A Class A or Class C provider pharmacy may establish a satellite pharmacy in a location that is not at the same location as a Class A or Class C pharmacy.

(2) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the satellite pharmacy including supervision of satellite pharmacy personnel and compliance with this section.

(3) A satellite pharmacy may not store bulk drugs and may only store prescription medications that have been previously verified and dispensed by the provider pharmacy.

(4) A Class C pharmacy that is a provider pharmacy dispensing outpatient prescriptions for a satellite pharmacy shall comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel, Operational Standards, and Records for Class A (Community) pharmacies) and this section.

(5) The provider pharmacy and the satellite pharmacy must have:

(A) the same owner; and

(B) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a non-dispensing function.

(d) Personnel.

(1) All individuals working at the satellite pharmacy shall be employees of the provider pharmacy and must report their employment to the board as such.

(2) A satellite pharmacy shall have sufficient pharmacists on duty to operate the satellite pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

(3) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for designating and delegating duties, other than those listed in paragraph (7) of this subsection, to pharmacy technicians and pharmacy technician trainees. Each pharmacist:

(A) shall verify the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees; and

(B) shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

(4) A pharmacist shall be physically present to directly supervise a pharmacy technician or pharmacy technician trainee who is entering prescription data into the data processing system. Each prescription entered into the data processing system shall be verified at the time of data entry.

(5) All pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(6) A pharmacist shall ensure that the drug is dispensed and delivered safely and accurately as prescribed. A pharmacist shall ensure the safety and accuracy of the portion of the process the pharmacist is performing.

(7) Duties, in a satellite pharmacy, that may only be performed by a pharmacist are as follows:

(A) receiving oral prescription drug orders and reducing these orders to writing, either manually or electronically;

(B) interpreting or clarifying prescription drug orders;

(C) communicating to the patient or patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment, the pharmacist deems significant, as specified in §291.33(c) of this title;

(D) communicating to the patient or the patient's agent on his or her request information concerning any prescription drugs dispensed to the patient by the pharmacy;

(E) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(F) interpreting patient medication records and performing drug regimen reviews; and

(G) performing a specific act of drug therapy management for a patient delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with the Medical Practice Act.

(8) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (7) of this subsection. However, a pharmacist may delegate to pharmacy technicians and pharmacy technician trainees any nonjudgmental technical duty associated with the preparation and distribution of prescription drugs provided:

(A) a pharmacist verifies the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees; and

(B) pharmacy technicians and pharmacy technician trainees are under the direct supervision of and responsible to a pharmacist.

(9) Pharmacy technicians and pharmacy technician trainees, in a satellite pharmacy, may perform only nonjudgmental technical duties associated with the preparation and distribution of prescription drugs as follows:

(A) initiating and receiving refill authorization requests;

(B) entering prescription data into a data processing system; and

(C) reconstituting medications.

(10) In a satellite pharmacy, the ratio of pharmacists to pharmacy technicians/pharmacy technician trainees may be 1:3, provided at least one of the three is a pharmacy technician and not a pharmacy technician trainee.

(11) All satellite pharmacy personnel shall wear identification tags or badges that bears the person's name and identifies him or her as a pharmacist, pharmacist intern, pharmacy technician, or pharmacy technician trainee.

(e) Operational requirements.

(1) Application for permission to provide satellite pharmacy services.

(A) A Class A or Class C pharmacy shall make application to the board to provide satellite pharmacy services. The application shall contain an affidavit with the notarized signatures of the pharmacist-in-charge and the person responsible for the on-site operation of the facility where the satellite pharmacy will be located and include the following:

(i) the name, address, and license number of the provider pharmacy;

(ii) the name and address of the facility where the satellite pharmacy will be located;

(iii) anticipated date of opening and hours of operation; and

(iv) copy of the lease agreement or alternatively, a notarized statement signed by the lessee and lessor certifying the existence of a lease.

(B) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license. The renewal petition shall contain the documentation required in subparagraph (A) of this paragraph except the notarized signature of the person responsible for the on-site operation of the facility where the satellite pharmacy will be located.

(C) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the satellite pharmacy.

(2) Notification requirements.

(A) A provider pharmacy shall notify the board in writing within ten days of a change of location, discontinuance of service, or closure of a satellite pharmacy that is operated by the pharmacy.

(B) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each satellite pharmacy if controlled substances are maintained at the satellite pharmacy.

(3) Environment.

(A) The satellite pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be clean and in good operating condition.

(B) A satellite pharmacy shall contain an area which is suitable for confidential patient counseling.

(i) Such counseling area shall:

(I) be easily accessible to both patient and pharmacists and not allow patient access to prescription drugs;

(II) be designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

(ii) In determining whether the area is suitable for confidential patient counseling and designed to maintain the confidentiality and privacy of the pharmacist/patient communication, the board may consider factors such as the following:

(I) the proximity of the counseling area to the check-out or cash register area;

(II) the volume of pedestrian traffic in and around the counseling area;

(III) the presence of walls or other barriers between the counseling area and other areas of the pharmacy; and

(IV) any evidence of confidential information being overheard by persons other than the patient or patient's agent or the pharmacist or agents of the pharmacist.

(C) The satellite pharmacy shall be properly lighted and ventilated.

(D) The temperature of the satellite pharmacy shall be maintained within a range compatible with the proper storage of drugs in compliance with the provisions of §291.33(f) of this title including the requirements for temperature. The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

(E) Animals, including birds and reptiles, shall not be kept within the pharmacy and in immediately adjacent areas under the control of the pharmacy. This provision does not apply to fish in aquar-

iums, guide dogs accompanying disabled persons, or animals for sale to the general public in a separate area that is inspected by local health jurisdictions.

(4) Security.

(A) A satellite pharmacy shall be under the continuous, physically present supervision of a pharmacist at all times the satellite pharmacy is open to provide pharmacy services.

(B) The satellite pharmacy shall be enclosed by walls, partitions or other means of floor-to-ceiling enclosure. In addition, to the security requirements outlined in §291.33(b)(2) of this title, satellite pharmacies shall have adequate security and procedures to

(i) prohibit unauthorized access;

(ii) comply with federal and state regulations; and

(iii) maintain patient confidentiality.

(C) Access to the satellite pharmacy shall be limited to pharmacists, pharmacy technicians, and pharmacy technician trainees employed by the provider pharmacy and who are designated in writing by the pharmacist-in-charge.

(D) The provider pharmacy shall have procedures that specify that prescriptions may only be delivered to the satellite pharmacy by the provider pharmacy and shall:

(i) be delivered in a sealed container with a list of the prescriptions delivered;

(ii) signed for on receipt by the pharmacist at the satellite pharmacy;

(iii) be checked by personnel designated by the pharmacist-in-charge to verify that the prescriptions sent by the provider pharmacy were actually received. The designated person who checks the order shall document the verification by signing and dating the list of prescriptions delivered.

(5) Prescription dispensing and delivery. A satellite pharmacy shall comply with the requirements outlines in §291.33(c) of this title with regard to prescription dispensing and delivery.

(6) Equipment and supplies. A satellite pharmacy shall have the following equipment and supplies:

(A) typewriter or comparable equipment;

(B) refrigerator, if storing drugs requiring refrigeration;

(C) metric-apothecary weight and measure conversion charts.

(7) Library. A reference library shall be maintained by the satellite pharmacy that includes the following in hard-copy or electronic format:

(A) current copies of the following:

(i) Texas Pharmacy Act and rules;

(ii) Texas Dangerous Drug Act and rules;

(iii) Texas Controlled Substances Act and rules; and

(iv) Federal Controlled Substances Act and rules (or official publication describing the requirements of the Federal Controlled Substances Act and rules);

(B) at least one current or updated reference from each of the following categories:

(i) patient information:

(I) United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient); or

(II) a reference text or information leaflets which provide patient information;

(ii) drug interactions: a reference text on drug interactions, such as Drug Interaction Facts. A separate reference is not required if other references maintained by the pharmacy contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken;

(iii) a general information reference text, such as:

(I) Facts and Comparisons with current supplements;

(II) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the Healthcare Provider);

(III) Clinical Pharmacology;

(IV) American Hospital Formulary Service with current supplements; or

(V) Remington's Pharmaceutical Sciences; and

(C) basic antidote information and the telephone number of the nearest Regional Poison Control Center.

(f) Records.

(1) Maintenance of records.

(A) Every record required to be kept and §291.34 of this title and under this section shall be;

(i) kept by the provider pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(ii) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(B) Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(i) the records maintained in the alternative system contain all of the information required on the manual record; and

(ii) the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(C) Prescription drug orders shall be maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(2) Prescriptions.

(A) Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(B) The provider pharmacy must maintain appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performed any processing at the satellite pharmacy.

(C) A provider pharmacy shall keep a record of all prescriptions sent and returned between the pharmacies separate from the records of the provider pharmacy and from any other satellite pharmacy's records.

(D) A satellite pharmacy shall keep a record of all prescriptions received and returned between the pharmacies.

§291.131. Pharmacies Compounding Non-Sterile Preparations.

(a) Purpose. Pharmacies compounding non-sterile preparations, prepackaging pharmaceutical products and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:

(1) compounding of non-sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies;

(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded non-sterile preparation in a Class A (Community), Class C (Institutional) , and Class E (Non-resident) pharmacies to a practitioner's office for office use by the practitioner;

(3) compounding and distribution of compounded non-sterile preparations by a Class A (Community) pharmacy for a Class C (Institutional) pharmacy; and

(4) compounding of non-sterile preparations by a Class C (Institutional) pharmacy and the distribution of the compounded preparations to other Class C (Institutional) pharmacies under common ownership.

(b) Definitions. In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Beyond-use date--The date or time after which the compounded non-sterile preparation shall not be stored or transported or begin to be administered to a patient. The beyond-use date is determined from the date or time when the preparation was compounded.

(2) Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.

(3) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner's prescription drug or medication order, based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under Section 562.154 or Chapter 563 of the Occupations Code.

(4) Hot water--The temperature of water from the pharmacy's sink maintained at 120 to 140 degrees F (49 to 60 C).

(5) Reasonable quantity--An amount of a compounded drug that:

(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office or facility before the beyond use date of the drug;

(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and

(C) for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

(6) SOPs--Standard operating procedures.

(7) USP/NF--The current edition of the United States Pharmacopeia/National Formulary.

(c) Personnel.

(1) Pharmacist-in-charge. In addition to the responsibilities for the specific class of pharmacy, the pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning non-sterile compounding:

(A) determining that all personnel involved in non-sterile compounding possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised;

(B) determining that all personnel involved in non-sterile compounding obtain continuing education appropriate for the type of compounding done by the personnel;

(C) assuring that the equipment used in compounding is properly maintained;

(D) maintaining an appropriate environment in areas where non-sterile compounding occurs; and

(E) assuring that effective quality control procedures are developed and followed.

(2) Pharmacists. Special requirements for non-sterile compounding.

(A) All pharmacists engaged in compounding shall:

(i) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised; and

(ii) obtain continuing education appropriate for the type of compounding done by the pharmacist.

(B) A pharmacist shall inspect and approve all components, drug product containers, closures, labeling, and any other materials involved in the compounding process.

(C) A pharmacist shall review all compounding records for accuracy and conduct in-process and final checks to ensure that errors have not occurred in the compounding process.

(D) A pharmacist is responsible for the proper maintenance, cleanliness, and use of all equipment used in the compounding process.

(3) Pharmacy technicians and pharmacy technician trainees. All pharmacy technicians and pharmacy technician trainees engaged in non-sterile compounding shall:

(A) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken;

(B) obtain continuing education appropriate for the type of compounding done by the pharmacy technician or pharmacy technician trainee; and

(C) perform compounding duties under the direct supervision of and responsible to a pharmacist.

(4) Training.

(A) All training activities shall be documented and covered by appropriate SOPs as outlined in subsection (d)(8)(A) of this section.

(B) All personnel involved in non-sterile compounding shall be well trained and must participate in continuing relevant training programs.

(d) Operational Standards.

(1) General requirements.

(A) Non-sterile drug preparations may be compounded in licensed pharmacies:

(i) upon presentation of a practitioner's prescription drug or medication order based on a valid pharmacist/patient/prescriber relationship;

(ii) in anticipation of future prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.

(B) Non-sterile compounding in anticipation of future prescription drug or medication orders must be based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared is stable for the anticipated shelf time.

(i) The pharmacist's professional judgment shall be based on the criteria used to determine a beyond-use date outlined in paragraph (5)(C) of this subsection.

(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time must be maintained and be available for inspection.

(iii) Any preparation compounded in anticipation of future prescription drug or medication orders shall be labeled. Such label shall contain:

(I) name and strength of the compounded preparation or list of the active ingredients and strengths;

(II) facility's lot number;

(III) beyond-use date as determined by the pharmacist using appropriate documented criteria as outlined in paragraph (5)(C) of this subsection; and

(IV) quantity or amount in the container.

(C) Commercially available products may be compounded for dispensing to individual patients provided the following conditions are met:

(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet patient's needs;

(ii) the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and

(iii) the prescribing practitioner has requested that the drug be compounded as described in subparagraph (D) of this paragraph.

(D) A pharmacy may not compound preparations that are essentially copies of commercially available products (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product) unless the prescribing practitioner specifically orders the strength or dosage form and specifies why the patient needs the particular strength or dosage form of the preparation. The prescribing practitioner shall provide documentation of a patient specific medical need and the preparation produces a clinically significant therapeutic response (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The methodology for documenting unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered, discontinued, or out-of-stock items. This documentation must be available in hard-copy or electronic format for inspection by the Board.

(E) A pharmacy may enter into an agreement to compound and dispense prescription/medication orders for another pharmacy provided the pharmacy complies with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

(F) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide non-sterile prescription compounding services, which may include specific drug products and classes of drugs.

(G) A pharmacy may not compound veterinary preparations for use in food producing animals except in accordance with federal guidelines.

(2) Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain a current copy, in hard-copy or electronic format, of Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations.

(3) Environment.

(A) Pharmacies regularly engaging in compounding shall have a designated and adequate area for the safe and orderly compounding of non-sterile preparations, including the placement of equipment and materials. Pharmacies involved in occasional compounding shall prepare an area prior to each compounding activity which is adequate for safe and orderly compounding.

(B) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of a drug compounding operation.

(C) A sink with hot and cold running water, exclusive of rest room facilities, shall be accessible to the compounding areas and

be maintained in a sanitary condition. Supplies necessary for adequate washing shall be accessible in the immediate area of the sink and include:

(i) soap or detergent; and

(ii) air-driers or single-use towels.

(D) If drug products which require special precautions to prevent contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its use for the preparation of other drug products, must be used in order to prevent cross-contamination.

(4) Equipment and Supplies. The pharmacy shall:

(A) have a Class A prescription balance, or analytical balance and weights which shall be properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy; and

(B) have equipment and utensils necessary for the proper compounding of prescription drug or medication orders. Such equipment and utensils used in the compounding process shall be:

(i) of appropriate design and capacity, and be operated within designed operational limits;

(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the desired result;

(iii) cleaned and sanitized immediately prior and after to each use; and

(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

(5) Labeling. In addition to the labeling requirements of the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following.

(A) The generic name(s) or the official name(s) of the principal active ingredient(s) of the compounded preparation.

(B) A statement that the preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement).

(C) A beyond-use date after which the compounded preparation should not be used. The beyond-use date shall be determined as outlined in Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations including the following:

(i) The pharmacist shall consider:

(I) physical and chemical properties of active ingredients;

(II) use of preservatives and/or stabilizing agents;

(III) dosage form;

(IV) storage containers and conditions; and

(V) scientific, laboratory, or reference data from a peer reviewed source and retained in the pharmacy. The reference data should follow the same preparation instructions for combining raw materials and packaged in a container with similar properties.

(ii) In the absence of stability information applicable for a specific drug or preparation, the following maximum beyond-use dates are to be used when the compounded preparation is packaged in tight, light-resistant containers and stored at controlled room temperatures.

(I) Nonaqueous liquids and solid formulations (Where the manufactured drug product is the source of active ingredient): 25% of the time remaining until the product's expiration date or 6 months, whichever is earlier.

(II) Water-containing formulations (Prepared from ingredients in solid form): Not later than 14 days when refrigerated between 2 - 8 degrees Celsius (36 - 46 degrees Fahrenheit).

(III) All other formulations: Intended duration of therapy or 30 days, whichever is earlier.

(iii) Beyond-use date limits may be exceeded when supported by valid scientific stability information for the specific compounded preparation.

(6) Written drug information. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing. A statement which indicates that the preparation was compounded by the pharmacy must be included in this written information. If there is no written information available, the patient should be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate the prescriber, concerning the drug.

(7) Drugs, components, and materials used in non-sterile compounding.

(A) Drugs used in non-sterile compounding shall be a USP/NF grade substances manufactured in an FDA-registered facility.

(B) If USP/NF grade substances are not available, or when food, cosmetics, or other substances are, or must be used, the substance shall be of a chemical grade in one of the following categories:

(i) Chemically Pure (CP);

(ii) Analytical Reagent (AR); or

(iii) American Chemical Society (ACS); or

(iv) Food Chemical Codex; or

(C) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.

(D) A manufactured drug product may be a source of active ingredient. Only manufactured drugs from containers labeled with a batch control number and a future expiration date are acceptable as a potential source of active ingredients. When compounding with manufactured drug products, the pharmacist must consider all ingredients present in the drug product relative to the intended use of the compounded preparation.

(E) All components shall be stored in properly labeled containers in a clean, dry area, under proper temperatures.

(F) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug product beyond the desired result.

(G) Components, drug product containers, and closures shall be rotated so that the oldest stock is used first.

(H) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product.

(I) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.

(8) Compounding process.

(A) All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed for:

(i) the facility;

(ii) equipment;

(iii) personnel;

(iv) preparation evaluation;

(v) quality assurance;

(vi) preparation recall;

(vii) packaging; and

(viii) storage of compounded preparations.

(B) Any compounded preparation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

(C) Any person with an apparent illness or open lesion that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, any materials involved in the compounding process, and drug products until the condition is corrected.

(D) Personnel engaged in the compounding of drug preparations shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, hair nets, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug preparations from contamination.

(E) At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(9) Quality Assurance.

(A) Initial formula validation. Prior to routine compounding of a non-sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a product that contains the stated amount of active ingredient(s).

(B) Finished preparation checks. The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded non-sterile preparations shall be inspected for accuracy of correct identities and amounts of ingredients, packaging, labeling, and expected physical appearance before the non-sterile preparations are dispensed.

(10) Quality Control.

(A) The pharmacy shall follow established quality control procedures to monitor the quality of compounded drug preparations for uniformity and consistency such as capsule weight variations, adequacy of mixing, clarity, or pH of solutions. When developing these procedures, pharmacy personnel shall consider the provisions of Chapter 795, concerning Pharmacy Compounding Non-Sterile Preparations, Chapter 1075, concerning Good Compounding Practices, and Chapter 1160, concerning Pharmaceutical Calculations in Prescription Compounding contained in the current USP/NF. Such procedures shall be documented and be available for inspection.

(B) Compounding procedures that are routinely performed, including batch compounding, shall be completed and verified according to written procedures. The act of verification of a compounding procedure involves checking to ensure that calculations, weighing and measuring, order of mixing, and compounding techniques were appropriate and accurately performed.

(C) Unless otherwise indicated or appropriate, compounded preparations are to be prepared to ensure that each preparation shall contain not less than 90.0 percent and not more than 110.0 percent of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume and not less than 90.0 percent and not more than 110.0 percent of the theoretically calculated weight or volume per unit of the preparation.

(e) Records.

(1) Maintenance of records. Every record required by this section shall be:

(A) kept by the pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(2) Compounding records.

(A) Compounding pursuant to patient specific prescription drug or medication orders. Compounding records for all compounded preparations shall be maintained by the pharmacy electronically or manually as part of the prescription drug or medication order, formula record, formula book, or compounding log and shall include:

(i) the date of preparation;

(ii) a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) and name(s) of the manufacturer(s) of the raw materials and the quantities of each;

(iii) signature or initials of the pharmacist or pharmacy technician or pharmacy technician trainee performing the compounding;

(iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting in-process and final checks of compounded preparations if pharmacy technicians or pharmacy technician trainees perform the compounding function;

(v) the quantity in units of finished preparations or amount of raw materials;

(vi) the container used and the number of units prepared;

(vii) a reference to the location of the following documentation which may be maintained with other records, such as quality control records:

(I) the criteria used to determine the beyond-use date; and

(II) documentation of performance of quality control procedures. Documentation of the performance of quality control procedures is not required if the compounding process is done pursuant to a patient specific order and involves the mixing of two or more commercially available oral liquids or commercially available preparations when the final product is intended for external use.

(B) Compounding records when batch compounding or compounding in anticipation of future prescription drug or medication orders.

(i) Master work sheet. A master work sheet shall be developed and approved by a pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work sheet shall be used as the preparation work sheet from which each batch is prepared and on which all documentation for that batch occurs. The master work sheet shall contain at a minimum:

(I) the formula;

(II) the components;

(III) the compounding directions;

(IV) a sample label;

(V) evaluation and testing requirements;

(VI) specific equipment used during preparation; and

(VII) storage requirements.

(ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall document the following:

(I) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;

(II) lot number or each component;

(III) component manufacturer/distributor or suitable identifying number;

(IV) container specifications;

(V) unique lot or control number assigned to batch;

(VI) beyond use date of batch-prepared preparations;

(VII) date of preparation;

(VIII) name, initials, or electronic signature of the person(s) involved in the preparation;

(IX) name, initials, or electronic signature of the responsible pharmacist;

(X) finished preparation evaluation and testing specifications, if applicable; and

(XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.

(f) Office Use Compounding and Distribution of Compounded Preparations to Class C Pharmacies or Veterinarians in Accordance with Section 563.054 of the Act.

(1) General.

(A) A pharmacy may dispense and deliver a reasonable quantity of a compounded preparation to a practitioner for office use by the practitioner in accordance with this subsection.

(B) A Class A (Community) pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations to a Class C (Institutional) pharmacy.

(C) A Class C (Institutional) pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations that the Class C pharmacy has compounded for other Class C pharmacies under common ownership.

(D) To dispense and deliver a compounded preparation under this subsection, a pharmacy must:

(i) verify the source of the raw materials to be used in a compounded drug;

(ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);

(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;

(iv) comply with all applicable competency and accrediting standards as determined by the board; and

(v) comply with the provisions of this subsection.

(2) Written Agreement. A pharmacy that provides non-sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:

(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded preparations may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except as authorized by Section 563.054 of the Act;

(B) require the practitioner or receiving pharmacy to include on a patient's chart, medication order, or medication administration record the lot number and beyond-use date of a compounded preparation administered to a patient; and

(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:

(i) a patient to report an adverse reaction or submit a complaint; and

(ii) the pharmacy to recall batches of compounded preparations.

(3) Recordkeeping.

(A) Maintenance of Records.

(i) Records of orders and distribution of non-sterile compounded preparations to a practitioner for office use or to a Class C (Institutional) pharmacy for administration to a patient shall:

(I) be kept by the pharmacy and be available, for at least two years from the date of the record, for inspecting and copying

by the board or its representative and to other authorized local, state, or federal law enforcement agencies;

(II) maintained separately from the records of products dispensed pursuant to a prescription or medication order; and

(III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(B) Orders. The pharmacy shall maintain a record of all non-sterile compounded preparations ordered by a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:

(i) date of the order;

(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the Class C pharmacy ordering the preparation; and

(iii) name, strength, and quantity of the preparation ordered.

(C) Distributions. The pharmacy shall maintain a record of all non-sterile compounded preparations distributed pursuant to an order to a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:

(i) date the preparation was compounded;

(ii) date the preparation was distributed;

(iii) name, strength and quantity in each container of the preparation;

(iv) pharmacy's lot number;

(v) quantity of containers shipped; and

(vi) name, address, and phone number of the practitioner or Class C pharmacy to whom the preparation is distributed.

(D) Audit Trail.

(i) The pharmacy shall store the order and distribution records of preparations for all non-sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a Class C pharmacy for administration to a patient in such a manner as to be able to provide a audit trail for all orders and distributions of any of the following during a specified time period.

(I) any strength and dosage form of a preparation (by either brand or generic name or both);

(II) any ingredient;

(III) any lot number;

(IV) any practitioner;

(V) any facility; and

(VI) any pharmacy, if applicable.

(ii) The audit trail shall contain the following information:

(I) date of order and date of the distribution;

(II) practitioner's name, address, and name of the Class C pharmacy, if applicable;

(III) name, strength and quantity of the preparation in each container of the preparation;

(IV) name and quantity of each active ingredient;

(V) quantity of containers distributed; and

(VI) pharmacy's lot number.

(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:

(A) name, address, and phone number of the compounding pharmacy;

(B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";

(C) name and strength of the preparation or list of the active ingredients and strengths;

(D) pharmacy's lot number;

(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;

(F) quantity or amount in the container;

(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(H) device-specific instructions, where appropriate.

(g) Recall Procedures.

(1) The pharmacy shall have written procedure for the recall of any compounded non-sterile preparations provided to a patient, to a practitioner for office use, or to a pharmacy for administration. The recall procedures shall require:

(A) notification to each practitioner, facility, and/or pharmacy to which the preparation was distributed;

(B) notification to each patient to whom the preparation was dispensed;

(C) quarantine of the product if there is a suspicion of harm to a patient; and

(D) a recall if there is probable or confirmed harm to a patient.

(2) If the pharmacy identifies a suspicion of, probable, or confirmed harm to a patient, the pharmacy shall immediately notify and provide information as required by the board to the following:

(A) the Texas Department of State Health Services, Drugs and Medical Devices Group, if the preparation is distributed for office use; and

(B) the board.

(3) The board may require a pharmacy to institute a recall if there is probable or confirmed harm to a patient.

§291.133. Pharmacies Compounding Sterile Preparations.

(a) Purpose. Pharmacies compounding sterile preparations, prepackaging pharmaceutical products, and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:

(1) compounding of sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies;

(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile preparation in a Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies to a practitioner's office for office use by the practitioner;

(3) compounding and distribution of compounded sterile preparations by a Class A (Community) pharmacy for a Class C (Institutional) pharmacy; and

(4) compounding of sterile preparations by a Class C (Institutional) pharmacy and the distribution of the compounded preparations to other Class C (Institutional) pharmacies under common ownership.

(b) Definitions. In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) ACPE--Accreditation Council for Pharmacy Education.

(2) Airborne particulate cleanliness class--The level of cleanliness specified by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For example:

(A) ISO Class 5 (formerly Class 100) is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100 particles 0.5 microns in diameter per cubic foot of air);

(B) ISO Class 7 (formerly Class 10,000) is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 10,000 particles 0.5 microns in diameter per cubic foot of air); and

(C) ISO Class 8 (formerly Class 100,000) is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100,000 particles 0.5 microns in diameter per cubic foot of air).

(3) Ancillary supplies--Supplies necessary for the preparation and administration of compounded sterile preparations.

(4) Anteroom--An ISO Class 8 or better area where personnel may perform hand hygiene and garbing procedures, staging of components, order entry, labeling, and other high-particulate generating activities. It is also a transition area that:

(A) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas; and

(B) reduces the need for the heating, ventilating and air conditioning (HVAC) control system to respond to large disturbances.

(5) Aseptic Processing--The technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during preparation.

(6) Automated compounding device--An automated device that compounds, measures, and/or packages a specified quantity of individual components in a predetermined sequence for a designated sterile preparation.

(7) Batch--A specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation cycle.

(8) Batch preparation compounding--Compounding of multiple sterile preparation units, in a single discrete process, by the same individual(s), carried out during one limited time period. Batch preparation/compounding does not include the preparation of multiple sterile preparation units pursuant to patient specific medication orders.

(9) Beyond-use date--The date or time after which the compounded sterile preparation shall not be stored or transported or begin to be administered to a patient. The beyond-use date is determined from the date or time the preparation is compounded.

(10) Biological Safety Cabinet, Class II--A ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered exhausted air for environmental protection.

(11) Buffer Area, Buffer or Core Room, Buffer or Clean Room Areas, Buffer Room Area, Buffer or Clean Area--An ISO Class 7 area where the primary engineering control area is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.

(12) Clean room--A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

(13) Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.

(14) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner's prescription drug or medication order based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under Section 562.154 or Chapter 563 of the Occupations Code.

(15) Compounding Aseptic Isolator--A form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment shall not occur unless it has first passed through a microbial retentive filter (HEPA minimum).

(16) Critical Area--A critical area is an ISO Class 5 environment.

(17) Critical Sites--Sterile ingredients of compounded sterile preparations and locations on devices and components used to prepare, package, and transfer compounded sterile preparations that provide opportunity for exposure to contamination.

(18) Cytotoxic--A pharmaceutical that has the capability of killing living cells.

(19) Device--An instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner.

(20) Disinfectant--A disinfectant is an agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial spores. It refers to substances applied to inanimate objects.

(21) Hot water--The temperature of water from the pharmacy's sink maintained at 120 to 140 degrees F (49 to 60 C).

(22) HVAC--Heating, ventilation, and air conditioning.

(23) Immediate use--A sterile preparation that is not prepared according to USP 797 standards (i.e. outside the pharmacy and most likely not by pharmacy personnel) which shall be stored for no longer than one hour after completion of the preparation.

(24) IPA--Isopropyl alcohol (2-propanol).

(25) Media-Fill Test--A media-fill test is used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as Soybean--Casein Digest Medium (SCDM) is substituted for the actual drug product to simulate admixture compounding. The issues to consider in the development of a media-fill test are the following: media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

(26) Multiple-Dose Container--A multiple-unit container for articles or preparations intended for potential administration only and usually contains antimicrobial preservatives. The beyond-use date for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.

(27) Negative Pressure Room--A room that is at a lower pressure compared to adjacent spaces and, therefore, the net flow of air is into the room.

(28) Office use--The administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 562 of the Act, or for administration or provision by a veterinarian in accordance with Section 563.054 of the Act.

(29) Pharmacy Bulk Package--A container of a sterile preparation for potential use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).

(30) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original container into unit dose packaging or a multiple dose container for distribution within a facility licensed as a Class C pharmacy or to other pharmacies under common ownership for distribution within those facilities. The term as defined does not prohibit the prepackaging of drug products for use within other pharmacy classes.

(31) Preparation or Compounded Sterile Preparation--A sterile admixture compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber; the article may or may not contain sterile products.

(32) Primary Engineering Control--A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding sterile preparations. Such devices include, but may not be limited to, laminar airflow workbenches, biological safety cabinets, and compounding aseptic isolators.

(33) Product--A product is a commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

(34) Positive Control--A quality assurance sample prepared to test positive for microbial growth.

(35) Positive Pressure Room--A room that is at a higher pressure compared to adjacent spaces and, therefore, the net airflow is out of the room.

(36) Quality assurance--The set of activities used to ensure that the process used in the preparation of sterile drug products lead to products that meet predetermined standards of quality.

(37) Quality control--The set of testing activities used to determine that the ingredients, components (e.g., containers), and final compounded sterile preparations prepared meet predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.

(38) Reasonable quantity--An amount of a compounded drug that:

(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office or facility before the beyond use date of the drug;

(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and

(C) for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

(39) Single-dose container--A container intended for a single use, other than single-dose vials and single-dose large volume potential solutions. Examples of single-dose containers include pre-filled syringes, cartridges, and fusion-sealed containers without preservatives.

(40) Single-dose vial--A vial intended for a single use. Exceptions to this definition would be single dose vials routinely used to compound total potential nutrition (TPN) preparations (e.g., sodium chloride, sodium acetate, sodium phosphate, potassium chloride, potassium acetate, potassium phosphate, calcium glucontae, magnesium sulfate, multivitamin for injection, multi-trace elements, ascorbic acid, folic acid, heparin, phytonadione, l-carnitine, cysteine, selenium, injectable zinc).

(41) Single-dose large volume parenteral (LVP) solution--LVP solutions (i.e., containers of solution of at least 1000 mL) routinely used for compounding sterile TPN preparations or for batch compounding (e.g., sterile water for injection (SWFI); 5%, 10%, and 70% dextrose in SWFI; 0.9% sodium chloride; 0.45% sodium chloride; 5% dextrose/0.9% sodium chloride; 5% dextrose/0.45% sodium chloride).

(42) SOPs--Standard operating procedures.

(43) Terminal Sterilization--The application of a lethal process, e.g., steam under pressure or autoclaving, to sealed final preparation containers for the purpose of achieving a predetermined sterility assurance level of usually less than 106, i.e., or a probability of less than one in one million of a non-sterile unit.

(44) USP/NF--The current edition of the United States Pharmacopeia/National Formulary.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. The pharmacy shall have a pharmacist-in-charge in compliance with the specific license classification of the pharmacy.

(B) Responsibilities. In addition to the responsibilities for the specific class of pharmacy, the pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning the compounding of sterile preparations:

(i) developing a system to ensure that all pharmacy personnel responsible for compounding and/or supervising the compounding of sterile preparations within the pharmacy receive appropriate education and training and competency evaluation;

(ii) determining that all pharmacists involved in compounding sterile preparations obtain continuing education appropriate for the type of compounding done by the pharmacist;

(iii) supervising a system to ensure appropriate procurement of drugs and devices and storage of all pharmaceutical materials including pharmaceuticals, components used in the compounding of sterile preparations, and drug delivery devices;

(iv) ensuring that the equipment used in compounding is properly maintained;

(v) developing a system for the disposal and distribution of drugs from the pharmacy;

(vi) developing a system for bulk compounding or batch preparation of drugs;

(vii) developing a system for the compounding, sterility assurance, quality assurance, and quality control of sterile preparations; and

(viii) if applicable, ensuring that the pharmacy has a system to dispose of hazardous waste in a manner so as not to endanger the public health.

(2) Pharmacists. Special requirements for compounding sterile preparations.

(A) All pharmacists engaged in compounding sterile preparations shall:

(i) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised; and

(ii) obtain continuing education appropriate for the type of compounding done by the pharmacist.

(B) A pharmacist shall inspect and approve all components, drug preparation containers, closures, labeling, and any other materials involved in the compounding process.

(C) A pharmacist shall review all compounding records for accuracy and conduct in-process and final checks to ensure that errors have not occurred in the compounding process.

(D) A pharmacist is responsible for the proper maintenance, cleanliness, and use of all equipment used in the compounding process.

(E) A pharmacist shall be accessible at all times to respond to patients' and other health professionals' questions and needs. Such access may be through a telephone or pager which is answered 24 hours a day.

(3) Pharmacy technicians and pharmacy technician trainees. Pharmacy technicians and pharmacy technician trainees may compound sterile preparations provided the pharmacy technicians and/or pharmacy technician trainees:

(A) have completed the education and training specified in paragraph (4) of this subsection; and

(B) are supervised by a pharmacist who has completed the training specified in paragraph (4) of this subsection, conducts in-process and final checks, and affixes his or her initials to the appropriate quality control records.

(4) Special education, training, and evaluation requirements for pharmacy personnel compounding or responsible for the direct supervision of pharmacy personnel compounding sterile preparations.

(A) General.

(i) All pharmacy personnel preparing sterile preparations shall receive didactic and experiential training and competency evaluation through demonstration, testing (written and practical) as outlined by the pharmacist-in-charge and described in the policy and procedure or training manual. Such training shall include instruction and experience in the following areas:

(I) aseptic technique;

(II) critical area contamination factors;

(III) environmental monitoring;

(IV) structure and engineering controls related to facilities;

(V) equipment and supplies;

(VI) sterile preparation calculations and terminology;

(VII) sterile preparation compounding documentation;

(VIII) quality assurance procedures;

(IX) aseptic preparation procedures including proper gowning and gloving technique;

(X) handling of cytotoxic and hazardous drugs, if applicable; and

(XI) general conduct in the controlled area.

(ii) The aseptic technique of each person compounding or responsible for the direct supervision of personnel compounding sterile preparations shall be observed and evaluated as satisfactory

through written and practical tests, and media-fill challenge testing, and such evaluation documented.

(iii) Although media-fill tests may be incorporated into the experiential portion of a training program, media-fill tests must be conducted at each pharmacy where an individual compounds sterile preparations. No preparation intended for patient use shall be compounded by an individual until the on-site media-fill tests test indicates that the individual can competently perform aseptic procedures, except that a pharmacist may temporarily compound sterile preparations and supervise pharmacy technicians compounding sterile preparations without media-fill tests provided the pharmacist:

(I) has completed a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE approved provider which provides 20 hours of instruction and experience in the areas listed in this subparagraph; and

(II) completes the on-site media-fill tests within seven days of commencing work at the pharmacy.

(iv) Media-fill tests procedures for assessing the preparation of specific types of sterile preparations shall be representative of all types of manipulations, products, risk levels, and batch sizes that personnel preparing that type of sterile preparation are likely to encounter.

(v) The pharmacist-in-charge shall ensure continuing competency of pharmacy personnel through in-service education, training, and media-fill tests to supplement initial training. Personnel competency shall be evaluated:

(I) during orientation and training prior to the regular performance of those tasks;

(II) whenever the quality assurance program yields an unacceptable result;

(III) whenever unacceptable techniques are observed; and

(IV) at least on an annual basis for low- and medium-risk level compounding, and every six months for high-risk level compounding.

(B) Pharmacists.

(i) All pharmacists who compound sterile preparations for administration to patients or supervise pharmacy technicians and pharmacy technician trainees compounding sterile preparations shall:

(I) complete through a single course, a minimum of 20 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph. Such training may be obtained through:

(-a-) completion of a structured on-the-job didactic and experiential training program at this pharmacy which provides 20 hours of instruction and experience in the areas listed in paragraph (1) of this subsection. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; or

(-b-) completion of a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE approved provider which provides 20 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph.

(II) possess knowledge about:

(-a-) aseptic processing;

(-b-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;

(-c-) chemical, pharmaceutical, and clinical properties of drugs;

(-d-) container, equipment, and closure system selection; and

(-e-) sterilization techniques.

(ii) The required experiential portion of the training programs specified in this subparagraph must be supervised by an individual who has already completed training as specified in subparagraph (B) or (C) of this paragraph.

(C) Pharmacy technicians and pharmacy technician trainees. In addition to specific qualifications for registration, all pharmacy technicians and pharmacy technician trainees who compound sterile preparations for administration to patients shall:

(i) have initial training obtained either through completion of:

(I) a single course, a minimum of 40 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph. Such training may be obtained through:

(-a-) completion of a structured on-the-job didactic and experiential training program at this pharmacy which provides 40 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; or

(-b-) completion of a course sponsored by an ACPE approved provider which provides 40 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph; or

(II) a training program which is accredited by the American Society of Health-System Pharmacists. Individuals enrolled in training programs accredited by the American Society of Health-System Pharmacists may compound sterile preparations in a licensed pharmacy provided:

(-a-) the compounding occurs only during times the individual is assigned to a pharmacy as a part of the experiential component of the American Society of Health-System Pharmacists training program;

(-b-) the individual is under the direct supervision of and responsible to a pharmacist who has completed training as specified in subparagraph (B) of this paragraph; and

(-c-) the supervising pharmacist conducts in-process and final checks.

(ii) acquire the required experiential portion of the training programs specified in this subparagraph under the supervision of an individual who has already completed training as specified in subparagraph (B) or (C) of this paragraph.

(D) Documentation of Training. The pharmacy shall maintain a record on each person who compounds sterile preparations. The record shall contain, at a minimum, a written record of initial and in-service training, continuing education, and the results of written and practical testing and media-fill testing of pharmacy personnel. The record shall be maintained and contain the following information:

(i) name of the person receiving the training or completing the testing or media-fill tests;

(ii) date(s) of the training, testing, or media-fill challenge testing;

(iii) general description of the topics covered in the training or testing or of the process validated;

(iv) name of the person supervising the training, testing, or media-fill challenge testing; and

(v) signature or initials of the person receiving the training or completing the testing or media-fill challenge testing and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or media-fill challenge testing of personnel.

(d) Operational Standards.

(1) General Requirements.

(A) Sterile preparations may be compounded in licensed pharmacies:

(i) upon presentation of a practitioner's prescription drug or medication order based on a valid pharmacist/patient/prescriber relationship;

(ii) in anticipation of future prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.

(B) Sterile compounding in anticipation of future prescription drug or medication orders must be based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared is stable for the anticipated shelf time.

(i) The pharmacist's professional judgment shall be based on the criteria used to determine a beyond-use date outlined in paragraph (5)(G) of this subsection.

(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time must be maintained and be available for inspection.

(iii) Any preparation compounded in anticipation of future prescription drug or medication orders shall be labeled. Such label shall contain:

(I) name and strength of the compounded preparation or list of the active ingredients and strengths;

(II) facility's lot number;

(III) beyond-use date as determined by the pharmacist using appropriate documented criteria as outlined in paragraph (5)(G) of this subsection;

(IV) quantity or amount in the container;

(V) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(VI) device-specific instructions, where appropriate.

(C) Commercially available products may be compounded for dispensing to individual patients provided the following conditions are met:

(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet patient's needs;

(ii) the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and

(iii) the prescribing practitioner has requested that the drug be compounded as described in subparagraph (D) of this paragraph.

(D) A pharmacy may not compound preparations that are essentially copies of commercially available products (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product) unless the prescribing practitioner specifically orders the strength or dosage form and specifies why the patient needs the particular strength or dosage form of the preparation. The prescribing practitioner shall provide documentation of a patient specific medical need and the preparation produces a clinically significant therapeutic response (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The methodology for documenting unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered, discontinued, or out-of-stock items. This documentation must be available in hard-copy or electronic format for inspection by the Board.

(E) A pharmacy may enter into an agreement to compound and dispense prescription/medication orders for another pharmacy provided the pharmacy complies with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

(F) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide sterile prescription compounding services, which may include specific drug preparations and classes of drugs.

(G) A pharmacy may not compound veterinary preparations for use in food producing animals except in accordance with federal guidelines.

(2) Microbial Contamination Risk Levels. Risk Levels for sterile compounded preparations shall be as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF and as listed below.

(A) Low-risk level compounded sterile preparations.

(i) Low-Risk conditions. Low-risk level compounded sterile preparations are those compounded under all of the following conditions.

(I) The compounded sterile preparations are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices.

(II) The compounding involves only transfer, measuring, and mixing manipulations with closed or sealed packaging systems that are preformed promptly and attentively.

(III) Manipulations are limited to aseptically opening ampuls, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices and packages of other sterile products.

(IV) For a low-risk preparation, in the absence of direct sterility testing results or appropriate information sources that justify different limits, the storage periods may not exceed the following periods: before administration, 48 hours at controlled room temperature, for not more than 14 days if stored at a cold temperature, and for 45 days if stored in a frozen state at minus 20 degrees Celsius or colder). For delayed activation device systems, the storage period begins when the device is activated.

(ii) Examples of Low-Risk Compounding. Examples of low-risk compounding include the following.

(I) Single volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampules shall be passed through a sterile filter to remove any glass particles.

(II) Manually measuring and mixing no more than three manufactured products to compound drug admixtures.

(B) Medium-risk level compounded sterile preparations.

(i) Medium-Risk Conditions. Medium-risk level compounded sterile preparations, are those compounded aseptically under low-risk conditions and one or more of the following conditions exists.

(I) Multiple individual or small doses of sterile products are combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions.

(II) The compounding process includes complex aseptic manipulations other than the single-volume transfer.

(III) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogenous mixing (e.g., reconstitution of intravenous immunoglobulin or other intravenous protein products).

(IV) The compounded sterile preparations do not contain broad spectrum bacteriostatic substances and they are administered over several days (e.g., an externally worn infusion device).

(V) For a medium-risk preparation, in the absence of direct sterility testing results or appropriate information sources that justify different limits the beyond use dates may not exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 30 hours at controlled room temperature, for not more than 7 days at a cold temperature, and for 45 days in solid frozen state at minus 20 degrees Celsius or colder.

(ii) Examples of medium-risk compounding. Examples of medium-risk compounding include the following.

(I) Compounding of total parenteral nutrition fluids using a manual or automated device during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.

(II) Filling of reservoirs of injection and infusion devices with multiple sterile drug products and evacuations of air from those reservoirs before the filled device is dispensed.

(III) Filling of reservoirs of injection and infusion devices with volumes of sterile drug solutions that will be administered over several days at ambient temperatures between 25 and 40 degrees Celsius (77 and 104 degrees Fahrenheit).

(IV) Transfer of volumes from multiple ampuls or vials into a single, final sterile container or product.

(C) High-risk level compounded sterile preparations.

(i) High-risk Conditions. High-risk level compounded sterile preparations are those compounded under any of the following conditions.

(I) Non-sterile ingredients, including manufactured products are incorporated or a non-sterile device is employed before terminal sterilization.

(II) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior to ISO Class 5. This includes storage in environments inferior to ISO Class 5 of opened or partially used packages of manufactured sterile products that lack antimicrobial preservatives.

(III) Non-sterile preparations are exposed no more than 6 hours before being sterilized.

(IV) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.

(V) For a high-risk preparation, in the absence of direct sterility testing results or appropriate information sources that justify different limits, the storage periods cannot exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 24 hours at controlled room temperature, for not more than 3 days at a cold temperature, and for 45 days in solid frozen state at minus 20 degrees or colder.

(VI) All non-sterile measuring, mixing, and purifying equipment is rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for high-risk compounding while assuring cleanliness. All high-risk compounded sterile aqueous solutions subjected to terminal sterilization are passed through a filter with a nominal porosity not larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter. Sterilization of high-risk level compounded sterile preparations by filtration shall be performed entirely within an ISO Class 5 or superior air quality environment.

(ii) Examples of high-risk compounding. Examples of high-risk compounding include the following.

(I) Dissolving non-sterile bulk drug powders to make solutions, which will be terminally sterilized.

(II) Exposing the sterile ingredients and components used to prepare and package compounded sterile preparations to room air quality worse than ISO Class 5.

(III) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is performed.

(IV) Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.

(3) Immediate Use Compounded Sterile Preparations. For the purpose of emergency or immediate patient care, compounded sterile preparations are exempted from the requirements described in this paragraph for low-risk, medium-risk, and high-risk level compounded sterile preparations when all of the following criteria are met.

(A) Only simple aseptic measuring and transfer manipulations are performed with not more than three sterile non-hazardous commercial drug and diagnostic radiopharmaceutical drug products, including an infusion or diluent solution.

(B) Unless required for the preparation, the preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour.

(C) Administration begins not later than one hour following the completion of preparing the compounded sterile preparation.

(D) When the compounded sterile preparations is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the compounded sterile preparation shall bear a label listing patient identification information such as name and identification number(s), the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact 1-hour beyond-use time and date.

(E) If administration has not begun within one hour following the completion of preparing the compounded sterile preparation, the compounded sterile preparation is promptly and safely discarded. Immediate use compounded sterile preparations shall not be stored for later use.

(F) Cytotoxic drugs shall not be prepared as immediate use compounded sterile preparations.

(4) Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain current or updated copies in hard-copy or electronic format of each of the following:

(A) a reference text on injectable drug preparations, such as Handbook on Injectable Drug Products;

(B) a specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy, e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs; and

(C) the United States Pharmacopeia/National Formulary or the USP Pharmacist's Pharmacopeia containing USP Chapter 797, Pharmaceutical Compounding - Sterile Preparations.

(5) Environment. Compounding facilities shall be physically designed and environmentally controlled to minimize airborne contamination of critical sites.

(A) Low and Medium Risk Preparations.

(i) Effective September 1, 2008, a pharmacy that prepares low- and medium-risk preparations shall have a designated room for the compounding of sterile preparations that is constructed to minimize the opportunities for particulate and microbial contamination. The designated room shall:

(I) be clean, well lit, and of sufficient size to support sterile compounding activities;

(II) be used only for the compounding of sterile preparations;

(III) be designed such that hand sanitizing and gowning occurs outside the buffer area but is accessible without use of the hands of the compounding personnel;

(IV) have non-porous and washable floors or floor covering to enable regular disinfection;

(V) be ventilated in a manner to avoid disruption from the HVAC system and room cross-drafts;

(VI) have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices (e.g., coved), nonshedding and resistant to damage by disinfectant agents.

(VII) have junctures of ceilings to walls coved or caulked to avoid cracks and crevices;

(VIII) have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning;

(IX) contain only the appropriate compounding supplies and not be used for bulk storage for supplies and materials. Objects that shed particles shall not be brought into the controlled area;

(X) contain an anteroom that provides at least an ISO class 8 air quality which may contain a sink that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination; and

(XI) contain a buffer zone or buffer room designed to maintain at least ISO Class 7 conditions. The following is applicable for the buffer area.

(-a-) There shall be some demarcation designation that delineates the anteroom or area from the buffer area.

(-b-) The buffer area shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation should be continuously monitored.

(-c-) A buffer room that provides a physical separation, through the use of walls, doors and pass-throughs shall have a minimum differential positive pressure of 0.02 to 0.05 inches water column.

(-d-) A buffer zone that is not physically separated from the anteroom shall employ the principle of displacement airflow as defined in Chapter 797, Pharmaceutical Compounding - Sterile Preparations, of the USP/NF, with limited access to personnel.

(-e-) The buffer area shall not contain sources of water (i.e., sinks) or floor drains.

(ii) The pharmacy shall prepare sterile pharmaceuticals in a primary engineering control device, such as a laminar air flow hood, biological safety cabinet, compounding aseptic isolator which is capable of maintaining at least ISO Class 5 conditions during normal activity.

(I) The primary engineering control shall:

(-a-) be located in the buffer area or room and placed in the buffer area in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system.

(-b-) be certified by an independent contractor according to the International Organization of Standardization (ISO) Classification of Particulate Matter in Room Air (ISO 14644-1) for operational efficiency at least every six months and when it is relocated, in accordance with the manufacturer's specifications; and

(-c-) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specification, and the inspection and/or replacement date documented.

(II) The compounding aseptic isolator must be placed in an ISO Class 7 cleanroom unless the compounding aseptic isolator meets all of the following conditions.

(-a-) The isolator must provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations.

(-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site must maintain ISO Class 5 levels during compounding operations.

(-c-) The pharmacy shall maintain documentation from the manufacturer that the compounding aseptic isolator meets this standard when located in worse than ISO Class 7 environments.

(B) High-risk Preparations. In addition to the requirements in subparagraph (A) of this paragraph, when high-risk preparations are compounded, the primary engineering control shall be located in a buffer room that provides a physical separation, through the use of walls, doors and pass-throughs and has a minimum differential positive pressure of 0.02 to 0.05 inches water column.

(C) Automated compounding device. If automated compounding devices are used, the pharmacy shall have a method to calibrate and verify the accuracy of automated compounding devices used in aseptic processing and document the calibration and verification on a routine basis, based on the manufacturer's recommendations.

(D) Cytotoxic drugs. In addition to the requirements specified in subparagraphs (A) and (B) of this paragraph, if the preparation is also cytotoxic, the following is applicable.

(i) General.

(I) All personnel involved in the compounding of cytotoxic products shall wear appropriate protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and appropriate gloving.

(II) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with aseptic techniques required for preparing sterile preparations.

(III) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.

(IV) Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and distributed in a manner to minimize patient contact with cytotoxic agents.

(ii) Primary engineering control device.

(I) Cytotoxic drugs must be prepared in a Class II or III biological safety cabinet or compounding aseptic isolator that is located in a ISO Class 7 room that is physically separated from other preparation areas and optimally has no less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 or better, anterooms, thus providing inward airflow to contain any airborne drug.

(II) If a compounding isolator is used outside of a cleanroom, the room must maintain a minimum negative pressure of 0.01-inch water column and have a minimum of 12 air changes per hour. Note that an anteroom leading to a negative pressure room shall meet at least ISO Class 7 criteria so that air drawn into the negative pressure environment is of the same ISO Class 7 quality. A pressure indictor shall be installed that can be readily monitored for correct room pressurization.

(III) Pharmacies that prepare very low volume of cytotoxic drugs (e.g., less than five preparations per week), the use of two tiers of containment, e.g., closed--system vial-transfer device within a biological safety cabinet or compounding aseptic isolator that are located in a non-negative pressure room is acceptable.

(E) Cleaning and disinfecting the sterile compounding areas. The following cleaning and disinfecting practices and frequencies apply to direct and contiguous compounding areas, which include ISO Class 5 compounding areas for exposure of critical sites as well as buffer rooms, anterooms, and ante-areas.

(i) The pharmacist-in-charge is responsible for developing written procedures for cleaning and disinfecting the direct and contiguous compounding areas and assuring the procedures are followed.

(ii) These procedures shall be conducted prior to and after each work shift (at a minimum of every 12 hours while the pharmacy is open) and when there are spills or environmental quality breaches.

(iii) Before compounding is performed, all items are removed from the direct and contiguous compounding areas and all surfaces are cleaned of loose material and residue from spills, followed by an application of a residue-free disinfecting agent (e.g., IPA), that is left on for a time sufficient to exert its antimicrobial effect.

(iv) Work surfaces near the direct and contiguous compounding areas in the buffer or clean area are cleaned of loose material and residue from spills, followed by an application of a residue-free disinfecting agent that is left on for a time sufficient to exert its antimicrobial effect.

(v) Floors in the buffer or clean area are cleaned by mopping at least once daily when no aseptic operations are in progress preceding from the buffer or clean room area to the anteroom area.

(vi) In the anteroom area, walls, ceilings, and shelving shall be cleaned monthly.

(vii) Supplies and equipment removed from shipping cartons must be wiped with a disinfecting agent, such as IPA. However, if supplies are received in sealed pouches, the pouches may be removed as the supplies are introduced into the buffer or clean area without the need to disinfect the individual supply items. No shipping or other external cartons may be taken into the buffer or clean area.

(viii) Storage shelving, emptied of all supplies, walls, and ceilings are cleaned and disinfected at planned intervals, monthly, if not more frequently.

(F) Security requirements. The pharmacy may authorize personnel to gain access to that area of the pharmacy containing dispensed sterile preparations, in the absence of the pharmacist, for the purpose of retrieving dispensed prescriptions to deliver to patients. If the pharmacy allows such after-hours access, the area containing the dispensed sterile pharmaceuticals shall be an enclosed and lockable area separate from the area containing undispensed prescription drugs. A list of the authorized personnel having such access shall be in the pharmacy's policy and procedure manual.

(G) Storage requirements and beyond-use dating.

(i) Storage requirements. All drugs shall be stored at the proper temperature and conditions, as defined in the USP/NF. The most commonly used definitions are as follows:

(I) freezer--A place where the temperature is maintained thermostatically between minus 25 degrees and minus 10 degrees Celsius (minus 13 degrees Fahrenheit and 14 degrees Fahrenheit).

(II) cold temperature--A temperature not exceeding 8 degrees Celsius (46 degrees Fahrenheit). A refrigerator is a cold place in which the temperature maintained thermostatically between 2 degrees and 8 degrees Celsius (36 degrees and 46 degrees Fahrenheit);

(III) cool--A temperature between 8 degrees and 15 degrees Celsius (46 degrees and 59 degrees Fahrenheit). An article for which storage in a cool place is directed may, alternatively, be stored in a refrigerator unless otherwise specified on the labeling; and

(IV) controlled room temperature--A temperature maintained thermostatically between 15 degrees and 30 degrees Celsius (59 degrees and 86 degrees Fahrenheit).

(ii) Beyond-use dating.

(I) Beyond-use dates for compounded sterile preparations shall be assigned based on professional experience, which shall include careful interpretation of appropriate information sources for the same or similar formulations.

(II) Beyond-use dates for compounded sterile preparations that are prepared strictly in accordance with manufacturers' product labeling must be those specified in that labeling, or from appropriate literature sources or direct testing.

(III) Beyond-use dates for compounded sterile preparations that lack justification from either appropriate literature sources or by direct testing evidence must be assigned as described in Chapter 797, Pharmaceutical Compounding - Sterile Preparations of the USP/NF.

(6) Equipment and supplies. Pharmacies compounding sterile preparations shall have the following equipment and supplies:

(A) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure that proper storage requirements are met, if sterile pharmaceuticals are stored in the refrigerator;

(B) a calibrated system or device to monitor the temperature where bulk chemicals are stored;

(C) if applicable, a Class A prescription balance, or analytical balance and weights. Such balance shall be properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy;

(D) equipment and utensils necessary for the proper compounding of sterile preparations. Such equipment and utensils used in the compounding process shall be:

(i) of appropriate design, appropriate capacity, and be operated within designed operational limits;

(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug preparation beyond the desired result;

(iii) cleaned and sanitized immediately prior to and after each use; and

(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;

(E) appropriate disposal containers for used needles, syringes, etc., and if applicable, hazardous waste from the preparation of hazardous drugs and/or biohazardous waste;

(F) appropriate packaging or delivery containers to maintain proper storage conditions for sterile preparations;

(G) infusion devices, if applicable; and

(H) all necessary supplies, including:

(i) disposable needles, syringes, and other supplies for aseptic mixing;

(ii) disinfectant cleaning solutions;

(iii) hand washing agents with bactericidal action;

(iv) disposable, lint free towels or wipes;

(v) appropriate filters and filtration equipment;

(vi) cytotoxic spill kits, if applicable; and

(vii) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.

(7) Labeling.

(A) Prescription drug or medication orders. In addition to the labeling requirements for the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following.

(i) The generic name(s) or the official name(s) of the principal active ingredient(s) of the compounded sterile preparation.

(ii) A statement that the compounded sterile preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement).

(iii) A beyond-use date after which the compounded sterile preparation shall not be used. The beyond-use date shall be determined as outlined in Chapter 797, Pharmacy Compounding - Sterile Preparations of the USP/NF, and paragraph (4) of this subsection.

(B) Batch. If the sterile pharmaceutical is compounded in a batch, the following shall also be included on the batch label.

(i) unique lot number assigned to the batch;

(ii) quantity;

(iii) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(iv) device-specific instructions, where appropriate.

(C) Pharmacy bulk package. The label of a pharmacy bulk package shall:

(i) state prominently "Pharmacy Bulk Package - Not for Direct Infusion;"

(ii) contain or refer to information on proper techniques to help ensure safe use of the preparation; and

(iii) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.

(8) Written drug information. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing. A statement which indicates that the preparation was compounded by the pharmacy must be included in this written information. If there is no written information available, the patient shall be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate, the prescriber, concerning the drug.

(9) Pharmaceutical Care Services. In addition to the pharmaceutical care requirements for the pharmacy's specific license classification, the following requirements must be met.

(A) Sterile preparations compounded pursuant to prescription drug orders (outpatients and long-term care facility patients).

(i) Primary provider. There shall be a designated physician primarily responsible for the patient's medical care. There

shall be a clear understanding between the physician, the patient, and the pharmacy of the responsibilities of each in the areas of the delivery of care, and the monitoring of the patient. This shall be documented in the patient medication record (PMR).

(ii) Patient training. The pharmacist-in-charge shall develop policies to ensure that the patient and/or patient's caregiver receives information regarding drugs and their safe and appropriate use, including instruction when applicable, regarding:

(I) appropriate disposition of hazardous solutions and ancillary supplies;

(II) proper disposition of controlled substances in the home;

(III) self-administration of drugs, where appropriate;

(IV) emergency procedures, including how to contact an appropriate individual in the event of problems or emergencies related to drug therapy; and

(V) if the patient or patient's caregiver prepares sterile preparations in the home, the following additional information shall be provided:

(-a-) safeguards against microbial contamination, including aseptic techniques for compounding intravenous admixtures and aseptic techniques for injecting additives to premixed intravenous solutions;

(-b-) appropriate storage methods, including storage durations for sterile pharmaceuticals and expirations of self-mixed solutions;

(-c-) handling and disposition of premixed and self-mixed intravenous admixtures; and

(-d-) proper disposition of intravenous admixture compounding supplies such as syringes, vials, ampules, and intravenous solution containers.

(iii) Pharmacist-patient relationship. It is imperative that a pharmacist-patient relationship be established and maintained throughout the patient's course of therapy. This shall be documented in the patient's medication record (PMR).

(iv) Patient monitoring. The pharmacist-in-charge shall develop policies to ensure that:

(I) the patient's response to drug therapy is monitored and conveyed to the appropriate health care provider; and

(II) the first dose of any new drug therapy is administered in the presence of an individual qualified to monitor for and respond to adverse drug reactions.

(B) Sterile preparation compounded pursuant to medication orders (inpatients).

(i) Education. The pharmacist-in-charge in cooperation with appropriate multi-disciplinary staff of the facility shall develop policies to ensure that:

(I) the patient and/or patient's caregiver receives information regarding drugs and their safe and appropriate use; and

(II) healthcare providers are provided with patient specific drug information.

(ii) Patient monitoring. The pharmacist-in-charge in cooperation with appropriate multi-disciplinary staff of the facility shall develop policies to ensure that the patient's response to drug therapy is monitored and conveyed to the appropriate healthcare provider.

(10) Drugs, components, and materials used in sterile compounding.

(A) Drugs used in sterile compounding shall be a USP/NF grade substances manufactured in an FDA-registered facility.

(B) If USP/NF grade substances are not available shall be of a chemical grade in one of the following categories:

(i) Chemically Pure (CP);

(ii) Analytical Reagent (AR);

(iii) American Chemical Society (ACS); or

(iv) Food Chemical Codex.

(C) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.

(D) All components shall:

(i) be manufactured in an FDA-registered facility; or

(ii) in the professional judgment of the pharmacist, be of high quality and obtained from acceptable and reliable alternative sources; and

(iii) stored in properly labeled containers in a clean, dry area, under proper temperatures.

(E) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug preparation beyond the desired result.

(F) Components, drug preparation containers, and closures shall be rotated so that the oldest stock is used first.

(G) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug preparation.

(H) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.

(11) Compounding process.

(A) Standard operating procedures (SOPs). All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed for:

(i) the facility;

(ii) equipment;

(iii) personnel;

(iv) preparation evaluation;

(v) quality assurance;

(vi) preparation recall;

(vii) packaging; and

(viii) storage of compounded sterile preparations.

(B) USP/NF. Any compounded formulation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

(C) Personnel Cleansing and Garbing.

(i) Any person with an apparent illness or open lesion that may adversely affect the safety or quality of a drug preparation being compounded shall be excluded from direct contact with components, drug preparation containers, closures, any materials involved in the compounding process, and drug products until the condition is corrected.

(ii) Before entering the clean area, compounding personnel must remove the following:

(I) personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests);

(II) all cosmetics, because they shed flakes and particles; and

(III) all hand, wrist, and other body jewelry.

(iii) The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment.

(iv) Personnel must don personal protective equipment and perform hand hygiene in an order that proceeds from the dirtiest to the cleanest activities as follows:

(I) Activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye shield. Eye shields are optional unless working with irritants like germicidal disinfecting agents.

(II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, personnel shall perform a hand hygiene procedure by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Personnel shall begin washing arms at the hands and continue washing to elbows for at least 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in the anteroom/ante-area.

(III) After completion of hand washing, personnel shall don non-shedding disposable gowns with sleeves that fit snugly around the wrists.

(IV) Gloves that form a continuous barrier with the gown shall be the last item donned before compounding begins.

(V) Gloves shall be disinfected by applying 70% IPA or appropriate disinfectant to all contact surface areas of the gloves and letting the gloves dry thoroughly. Routine application of 70% IPA shall occur throughout the compounding day and whenever nonsterile surfaces are touched.

(VI) When compounding personnel must temporarily exit the ISO Class 7 environment during a work shift, the exterior gown, if not visibly soiled, may be removed and retained in the ISO Class 8 anteroom/ante-area, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face mask/eye shield, and gloves must be replaced with new ones before re-entering the ISO Class 7 clean environment along with performing proper hand hygiene.

(D) At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(12) Quality Assurance.

(A) Initial Formula Validation. Prior to routine compounding of a sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a product that is sterile and that contains the stated amount of active ingredient(s).

(i) Low risk preparations.

(I) Quality assurance practices include, but are not limited to the following:

(-a-) Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality.

(-b-) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments and goggles.

(-c-) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.

(-d-) Visual inspection of compounded sterile preparations to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually by each person authorized to compound in a low-risk level under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low-risk level sterile produce. Once begun, this test is completed without interruption within an ISO Class 5 air quality environment. Three sets of four 5-milliliter aliquots of sterile Soybean--Casein Digest Medium are transferred with the same sterile 10-milliliter syringe and vented needle combination into separate sealed, empty, sterile 30-milliliter clear vials (i.e., four 5-milliliter aliquots into each of three 30-milliliter vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.

(ii) Medium risk preparations.

(I) Quality assurance procedures for medium-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations, as well as a more challenging media-fill test passed annually, or more frequently.

(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. This test is completed without interruption within an ISO Class 5 air quality environment. Six 100-milliliter aliquots of sterile Soybean--Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-milliliter syringe and 18-gauge needle combination is used to exchange two 5-milliliter aliquots of medium from one container to the other container in the pair. For example, after a 5-milliliter aliquot from the first container is added to the second container in the pair, the second container is agitated for 10 seconds, then a 5-milliliter aliquot is removed and returned to the first container in the pair. The first container is then agitated for 10 seconds, and the next 5-milliliter aliquot is transferred from it back to the second container in the pair. Following the two 5-milliliter aliquot exchanges in each pair of containers, a 5-milliliter aliquot of medium from each container is aseptically injected into a sealed, empty, sterile

10-milliliter clear vial, using a sterile 10-milliliter syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.

(iii) High risk preparations.

(I) Procedures for high-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations. In addition, a media-fill test that represents high-risk level compounding is performed twice a year by each person authorized to compound high-risk level compounded sterile preparations.

(II) Example of a Media-Fill Test Procedure Compounded Sterile Preparations Sterilized by Filtration. This test, or an equivalent test, is performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level compounded sterile preparations. Note: Sterility tests for autoclaved compounded sterile preparations are not required unless they are prepared in batches of more than 25 units. This test is completed without interruption in the following sequence:

(-a-) Dissolve 3 grams of nonsterile commercially available Soybean--Casein Digest Medium in 100 milliliters of non-bacteriostatic water to make a 3% non-sterile solution.

(-b-) Draw 25 milliliters of the medium into each of three 30-milliliter sterile syringes. Transfer 5 milliliters from each syringe into separate sterile 10-milliliter vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.

(-c-) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron porosity filter unit and a 20-gauge needle to each syringe. Inject the next 10 milliliters from each syringe into three separate 10-milliliter sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20 to 35 degrees Celsius. Inspect for microbial growth over 14 days as described in Chapter 797 Pharmaceutical Compounding - Sterile Preparations, of the USP/NF.

(B) Finished preparation release checks and tests.

(i) High-risk level compounded sterile preparations. All high-risk level compounded sterile preparations that are prepared in groups of more than 25 identical individual single-dose packages (such as ampuls, bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than 12 hours at 2 - 8 degrees Celsius (36 - 46 degrees Fahrenheit) and longer than six hours at warmer than 8 degrees Celsius (46 degrees Fahrenheit) before they are sterilized shall be tested to ensure they are sterile and do not contain excessive bacterial endotoxins as specified in Chapter 71, Sterility Tests of the USP/NF.

(ii) All compounded sterile preparations that are intended to be solutions must be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed.

(iii) The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded sterile preparations at all contamination risk levels shall be inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.

(13) Quality control.

(A) Quality control procedures. The pharmacy shall follow established quality control procedures to monitor the compounding environment and quality of compounded drug preparations for conformity with the quality indicators established for the preparation. When developing these procedures, pharmacy personnel shall consider the provisions of Chapter 797, Pharmaceutical Compounding - Sterile Preparations, Chapter 1075, Good Compounding Practices, and Chapter 1160, Pharmaceutical Calculations in Prescription Compounding of the current USP/NF. Such procedures shall be documented and be available for inspection.

(B) Verification of compounding accuracy and sterility.

(i) The accuracy of identities, concentrations, amounts, and purities of ingredients in compounded sterile preparations shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.

(ii) If the correct identify, purity, strength, and sterility of ingredients and components of compounded sterile preparations cannot be confirmed such ingredients and components shall be discarded immediately.

(iii) If individual ingredients, such as bulk drug substances, are not labeled with expiration dates, when the drug substances are stable indefinitely in their commercial packages under labeled storage conditions, such ingredients may gain or lose moisture during storage and use and shall require testing to determine the correct amount to weigh for accurate content of active chemical moieties in compounded sterile preparations.

(e) Records.

(1) Maintenance of records. Every record required under this section must be:

(A) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(2) Compounding records.

(A) Compounding pursuant to patient specific prescription drug or medication orders. Compounding records for all compounded pharmaceuticals shall be maintained by the pharmacy electronically or manually as part of the prescription drug or medication order, formula record, formula book, or compounding log and shall include:

(i) the date of preparation;

(ii) a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of each;

(iii) signature or initials of the pharmacist or pharmacy technician or pharmacy technician trainee performing the compounding;

(iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting in-process and finals checks of compounded pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the compounding function;

(v) the quantity in units of finished products or amount of raw materials;

(vi) the container used and the number of units prepared; and

(vii) a reference to the location of the following documentation which may be maintained with other records, such as quality control records:

(I) the criteria used to determine the beyond-use date; and

(II) documentation of performance of quality control procedures.

(B) Compounding records when batch compounding or compounding in anticipation of future prescription drug or medication orders.

(i) Master work sheet. A master work sheet shall be developed and approved by a pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work sheet shall be used as the preparation work sheet from which each batch is prepared and on which all documentation for that batch occurs. The master work sheet shall contain at a minimum:

(I) the formula;

(II) the components;

(III) the compounding directions;

(IV) a sample label;

(V) evaluation and testing requirements;

(VI) specific equipment used during preparation; and

(VII) storage requirements.

(ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall document the following:

(I) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;

(II) lot number for each component;

(III) component manufacturer/distributor or suitable identifying number;

(IV) container specifications (e.g., syringe, pump cassette);

(V) unique lot or control number assigned to batch;

(VI) expiration date of batch-prepared preparations;

(VII) date of preparation;

(VIII) name, initials, or electronic signature of the person(s) involved in the preparation;

(IX) name, initials, or electronic signature of the responsible pharmacist;

(X) finished preparation evaluation and testing specifications, if applicable; and

(XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.

(f) Office Use Compounding and Distribution of Compounded Preparations to Class C Pharmacies or Veterinarians in Accordance with Section 563.054 of the Act.

(1) General.

(A) A pharmacy may dispense and deliver a reasonable quantity of a compounded preparation to a practitioner for office use by the practitioner in accordance with this subsection.

(B) A Class A (Community) pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations to a Class C (Institutional) pharmacy.

(C) A Class C (Institutional) pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations that the Class C pharmacy has compounded for other Class C pharmacies under common ownership.

(D) To dispense and deliver a compounded preparation under this subsection, a pharmacy must:

(i) verify the source of the raw materials to be used in a compounded drug;

(ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);

(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;

(iv) comply with all applicable competency and accrediting standards as determined by the board; and

(v) comply with the provisions of this subsection.

(2) Written Agreement. A pharmacy that provides sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:

(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded drugs may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except as authorized by Section 563.054 of the Act;

(B) require the practitioner or receiving pharmacy to include on a patient's chart, medication order or medication administration record the lot number and beyond-use date of a compounded preparation administered to a patient;

(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:

(i) a patient to report an adverse reaction or submit a complaint; and

(ii) the pharmacy to recall batches of compounded preparations.

(3) Recordkeeping.

(A) Maintenance of Records.

(i) Records of orders and distribution of sterile compounded preparations to a practitioner for office use or to a Class C pharmacy for administration to a patient shall:

(I) be kept by the pharmacy and be available, for at least two years from the date of the record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies;

(II) maintained separately from the records of products dispensed pursuant to a prescription or medication order; and

(III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.

(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(B) Orders. The pharmacy shall maintain a record of all sterile compounded preparations ordered by a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:

(i) date of the order;

(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the Class C Pharmacy ordering the preparation; and

(iii) name, strength, and quantity of the preparation ordered.

(C) Distributions. The pharmacy shall maintain a record of all sterile compounded preparations distributed pursuant to an order to a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:

(i) date the preparation was compounded;

(ii) date the preparation was distributed;

(iii) name, strength and quantity in each container of the preparation;

(iv) pharmacy's lot number;

(v) quantity of containers shipped; and

(vi) name, address, and phone number of the practitioner or Class C Pharmacy to whom the preparation is distributed.

(D) Audit Trail.

(i) The pharmacy shall store the order and distribution records of preparations for all sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a Class C pharmacy for administration to a patient in such a manner as to be able to provide a audit trail for all orders and distributions of any of the following during a specified time period.

(I) any strength and dosage form of a preparation (by either brand or generic name or both);

(II) any ingredient;

(III) any lot number;

(IV) any practitioner;

(V) any facility; and

(VI) any pharmacy, if applicable.

(ii) The audit trail shall contain the following information:

(I) date of order and date of the distribution;

(II) practitioner's name, address, and name of the Class C pharmacy, if applicable;

(III) name, strength and quantity of the preparation in each container of the preparation;

(IV) name and quantity of each active ingredient;

(V) quantity of containers distributed; and

(VI) pharmacy's lot number;

(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:

(A) name, address, and phone number of the compounding pharmacy;

(B) the statement: "For Institutional or Office Use Only - Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";

(C) name and strength of the preparation or list of the active ingredients and strengths;

(D) pharmacy's lot number;

(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;

(F) quantity or amount in the container;

(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(H) device-specific instructions, where appropriate.

(g) Recall Procedures.

(1) The pharmacy shall have written procedure for the recall of any compounded sterile preparations provided to a patient, to a practitioner for office use, or to a pharmacy for administration. The recall procedures shall require:

(A) notification to each practitioner, facility, and/or pharmacy to which the preparation was distributed;

(B) notification to each patient to whom the preparation was dispensed;

(C) quarantine of the product if there is a suspicion of harm to a patient; and

(D) a recall if there is probable or confirmed harm to a patient.

(2) If the pharmacy identifies a suspicion of, probable, or confirmed harm to a patient, the pharmacy shall immediately notify and provide information as required by the board to the following:

(A) the Texas Department of State Health Services, Drugs and Medical Devices Group, if the preparation is distributed for office use; and

(B) the board.

(3) The board may require a pharmacy to institute a recall if there is probable or confirmed harm to a patient.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702243
Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 305-8028

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CHAPTER 295. PHARMACISTS

22 TAC §295.5, §295.9

The Texas State Board of Pharmacy proposes amendments to §295.5, concerning Pharmacist License or Renewal Fees and §295.9, concerning Inactive License. The proposed amendments to §295.5, if adopted, will raise pharmacist license fees based on increased expenses. The proposed amendments to §295.9, if adopted, require pharmacists wanting to reactivate an inactive license to submit proof of completion of 30 hours of approved continuing education.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the amendments are in effect, there will be fiscal implications for state government as a result of enforcing or administering the amended sections as follows:

Revenue Increase

FY2008 = $546,771

FY2009 = $596,496

FY2010 = $596,496

FY2011 = $596,496

FY2012 = $596,496

There are no anticipated fiscal implications for local government.

Ms. Dodson has determined that, for each year of the first five year period the amendments will be in effect, the public benefit anticipated as a result of enforcing the amended sections will be assuring that the Texas State Board of Pharmacy is adequately funded to carry out its mission. The effect on large, small or micro-businesses (pharmacies) will be the same as the economic cost to an individual, if the pharmacy chooses to pay the fee for the individual.

Economic cost to persons who are required to comply with the amended sections will be an increase of $51 for an initial registration and an increase of $51 for the renewal of a registration.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, FAX (512) 305-8082. Comments must be received by 5:00 p.m., July 30, 2007.

The amendments are proposed under §§551.002, 554.051, 559.101 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act. The Board interprets §559.101 as authorizing the Board to adopt rules regarding inactive licenses.

The statutes affected by the amendments: Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§295.5. Pharmacist License or Renewal Fees.

(a) (No change.)

(b) Initial License Fee.

(1) The fee for the initial license shall be $239 [~~$191~~] for a two year registration and for processing the application and issuance of the pharmacist license as authorized by the Act, §554.006.

(2) In addition, the following fees shall be collected:

(A) $13 [~~$10~~] surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act, §564.051;

(B) - (C) (No change.)

(3) (No change.)

(c) Renewal Fee.

(1) The fee for biennial renewal of a pharmacist license shall be $239 [~~$191~~] for processing the application and issuance of the pharmacist license as authorized by the Act, §554.006.

(2) In addition, the following fees shall be collected:

(A) $13 [~~$10~~] surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act, §564.051;

(B) - (C) (No change.)

(d) - (e) (No change.)

§295.9. Inactive License.

(a) - (b) (No change.)

(c) Reactivation of an inactive license.

(1) A holder of a license that is on inactive status may return the license to active status by:

(A) (No change.)

(B) providing copies of completion certificates from approved continuing education programs as specified in §295.8(e) of this title (relating to Continuing Education Requirements) for 30 hours [~~the number of hours that would otherwise have been required for the renewal of the license, up to 45 hours~~]. Approved continuing education earned within two years prior to the licensee applying for the return to active status may be applied toward the continuing education requirement for reactivation of the license but may not be counted toward subsequent renewal of the license; and

(C) (No change.)

(2) If the application for reactivation of the license is made at the time of license renewal, the applicant shall pay the license renewal fee specified in §295.5 of this title (relating to Pharmacist License or Renewal Fees). If the application for reactivation of the license is made at a time other than the time of license renewal, the applicant shall pay the fee for issuance of an amended license to practice pharmacy as specified in §295.5(e) [~~(d)~~] of this title (relating to Pharmacist License or Renewal Fees).

(3) In an emergency caused by a natural or manmade disaster or any other exceptional situation that causes an extraordinary demand for pharmacist services, the executive director of the board, in his/her discretion, may allow pharmacists whose license has been inactive for no more than two years to reactivate their license prior to obtaining the required continuing education specified in paragraph (1)(B) [~~(2)~~] of this subsection, provided the pharmacist completes the continuing education requirement within six months of reactivation of the license. If the required continuing education is not provided within six months, the license shall return to an inactive status.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

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Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 305-8028

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CHAPTER 297. PHARMACY TECHNICIANS AND PHARMACY TECHNICIAN TRAINEES

22 TAC §297.3, §297.4

The Texas State Board of Pharmacy proposes amendments to §297.3, concerning Registration Requirements and §297.4, concerning Fees. The proposed amendments to §297.3, if adopted, will recognize the abbreviation "Ph.T.R." to be used by registered pharmacy technicians. The proposed amendments to §297.4 will raise pharmacy technician registration fees based on increased expenses.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the amendments are in effect, there will be fiscal implications for state government as a result of enforcing or administering the amended sections as follows:

Revenue Increase

FY2008 = $142,208

FY2009 = $155,000

FY2010 = $155,000

FY2011 = $155,000

FY2012 = $155,000

There are no anticipated fiscal implications for local government.

Ms. Dodson has determined that, for each year of the first five year period the amendments will be in effect, the public benefit anticipated as a result of enforcing the amended sections will be assuring that the Texas State Board of Pharmacy is adequately funded to carry out its mission. The effect on large, small or micro-businesses (pharmacies) will be the same as the economic cost to an individual, if the pharmacy chooses to pay the individual fee.

Economic cost to persons who are required to comply with the amended sections will be an increase of $10 for an initial registration and an increase of $10 for the renewal of a registration.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, FAX (512) 305-8082. Comments must be received by 5:00 p.m., July 30, 2007.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by the amendments: Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§297.3. Registration Requirements.

(a) - (d) (No change.)

(e) An individual may use the title "Registered Pharmacy Technician" or "Ph.T.R." if the individual is registered as a pharmacy technician in this state.

§297.4. Fees.

(a) (No change.)

(b) Pharmacy technician.

(1) (No change.)

(2) Initial Registration Fee.

(A) The fee for initial registration shall be $64 [~~$54~~] for a two year registration and is composed of the following fees:

(i) $56 [~~$46~~] for processing the application and issuance of the pharmacy technician registration as authorized by the Act, §568.005;

(ii) - (iii) (No change.)

(B) (No change.)

(3) Renewal Fee. The fee for biennial renewal of a pharmacy technician registration shall be $61 [~~$51~~] and is composed of the following:

(A) $56 [~~$46~~] for processing the application and issuance of the pharmacy technician registration as authorized by the Act, §568.005;

(B) - (C) (No change.)

(c) (No change.)

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702218

Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 305-8028

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TITLE 31. NATURAL RESOURCES AND CONSERVATION

PART 17. TEXAS STATE SOIL AND WATER CONSERVATION BOARD

CHAPTER 520. DISTRICT OPERATIONS
SUBCHAPTER B. REQUIREMENTS TO RECEIVE STATE FUNDS OR ADMINISTER STATE PROGRAMS

31 TAC §§520.11 - 520.13

The Texas State Soil and Water Conservation Board (State Board) proposes new Chapter 520, District Operations, Subchapter B, Requirements To Receive State Funds or Administer State Programs, §§520.11 - 520.13, concerning agency administration of fiscal responsibilities. Specifically, these new rules provide the agency greater oversight for the funds that are granted or provided to soil and water conservation districts and to have increased oversight for the programs that are administered by soil and water conservation districts for this agency.

Mr. Kenny Zaijcek, Fiscal Officer, State Board has determined that for the first five-year period there will be no fiscal implications for state or local government as a result of administering these new rules.

Mr. Zaijcek has also determined that for the first five-year period the new rules are in effect, the public benefit anticipated as a result of administering the rules will be a greater exercise of internal controls for the handling of public funds by the State Board and individual soil and water conservation districts.

There are no anticipated costs to small businesses or individuals resulting from the new rules.

Comments on the proposed new rules may be submitted in writing to Rex Isom, Executive Director, Texas State Soil and Water Conservation Board, P.O. Box 658, Temple, Texas 76503, (254) 773-2250 ext.231.

The new rules are proposed under the Agriculture Code of Texas, Title 7, Chapter 201, §201.020, which authorizes the State Board to adopt rules that are necessary for the performance of its functions under the agriculture Code.

No other statutes, articles, or codes are affected by the proposed new rules.

§520.11. Policy Statement.

It is the policy of the State Soil and Water Conservation Board for soil and water conservation districts that receive state funds or administer programs for the state to implement internal controls for the handling of public funds and to conduct their board meetings in accordance with applicable laws and regulations.

§520.12. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) District--A soil and water conservation district created under the Agriculture Code of Texas, Chapter 201.

(2) State Board--The Texas State Soil and Water Conservation Board created under the Agriculture Code of Texas, Chapter 201.

§520.13. District Participation in State Board Programs.

(a) In accordance with Chapter 201, Agriculture Code of Texas, the State Board may allocate available funds to districts and may designate particular districts to administer certain programs and may adopt rules to carry out the programs.

(b) In order to be designated to administer certain programs and to receive funds and/or cost share assistance from the State Board, a district must provide evidence to the State Board that:

(1) it is conducting regularly scheduled meetings that are timely to properly handle financial and contractual obligations, and

(2) it is implementing internal controls for handling public funds that complies with Chapter 201, Agriculture Code, other applicable laws and regulations and State Board guidance documents, including the Manual of Fiscal Operations.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702239
Mel Davis
Special Projects Coordinator
Texas State Soil and Water Conservation Board
Earliest possible date of adoption: July 15, 2007
For further information, please call: (254) 773-2250 x252

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TITLE 37. PUBLIC SAFETY AND CORRECTIONS

PART 6. TEXAS DEPARTMENT OF CRIMINAL JUSTICE

CHAPTER 151. GENERAL PROVISIONS

37 TAC §151.4

The Texas Board of Criminal Justice (TBCJ) proposes amendments to §151.4, Public Testimony and Comments to the Texas Board of Criminal Justice. The proposed amendments are necessary to clarify procedures for public presentations and comments on topics under the jurisdiction of the TBCJ.

Charles Marsh, Chief Financial Officer for the Texas Department of Criminal Justice, has determined that for the first five (5) years the rule will be in effect, enforcing or administering the rule will not have foreseeable implications related to costs or revenues for state or local government.

Mr. Marsh has also determined that, for the first five (5) year period, there will not be an economic impact on persons required to comply with the rule. There will not be an effect on small or micro businesses. The anticipated public benefit, as a result of enforcing the rule, will be to ensure the public has an opportunity for public presentations and comments to the TBCJ.

Comments should be directed to Melinda Hoyle Bozarth, General Counsel, Texas Department of Criminal Justice, P.O. Box 13084, Austin, Texas 78711, Melinda.Bozarth@tdcj.state.tx.us. Written comments from the general public should be received within 30 days of the publication of this rule.

The amendments are proposed under Texas Government Code, §492.007, §492.013 and Chapter 551.

Cross Reference to Statutes: Texas Government Code, §492.007, §492.013 and Chapter 551.

§151.4. Public Presentations [~~Testimony~~] and Comments to the Texas Board of Criminal Justice.

(a) Policy. The Texas Board of Criminal Justice (TBCJ or Board) is committed to providing [~~provide~~] access and opportunity for public presentations and comments as provided for in this rule. [~~testimony on items that are part of the Board's posted agenda as provided for in this subsection and in subsection (b) of this section. The Board also invites public comment on issues within the jurisdiction of the Board as provided for in this subsection and in subsection (c) of this section.~~] Persons not employed by or under contract with [~~outside~~] the Texas Department of Criminal Justice (TDCJ or Agency), [~~agency~~] who wish to have items placed on the Board's posted [~~Board~~] agenda, shall [~~are invited to~~] follow the procedures set forth [~~procedure~~] in subsection (h) [~~(d)~~] of this rule [~~section~~]. Public presentations [~~testimony~~] and [~~public~~] comments shall be:

(1) subject to the requirements and restrictions of subsections (b), (c), (d), (e), (f)[~~,~~] and (g) [~~and (h)~~] of this rule [~~section~~];

(2) pertinent to issues under the jurisdiction of the Board, as determined by the Board Chairman and the TDCJ General Counsel; and

(3) pertinent to [~~TDCJ~~] policies, procedures, standards[~~,~~] and rules[~~,~~] of the TDCJ. Disputes [~~while actual disputes~~] that are appropriately [~~properly~~] the subject of the employee grievance system, the employee disciplinary system, the offender [~~inmate~~] grievance system, the offender [~~inmate~~] disciplinary system[~~,~~] or comments regarding pending litigation shall be addressed through those processes.

(b) Definitions.

(1) Public presentations--presentations made by the public to the Board regarding topics posted on a Board meeting agenda that has been filed with and published by the *Texas Register* and as provided for in subsection (c) of this rule.

(2) Public comments--comments made by the public on non-posted Board agenda topics and as provided for in subsection (d) of this rule.

(c) [~~(b)~~] Public presentations. [~~testimony on posted agenda topics.~~] Persons who desire to make public presentations [~~testimony~~] to the Board on posted agenda topics shall [~~must~~] provide, on the date of the meeting, a completed registration card to onsite Board office [~~the Board's support~~] staff at least ten (10) minutes prior to the meeting's posted start time. Registration cards shall be made available at the entry to the room [~~place~~] where the Board's scheduled meeting is [~~to be~~] held. [~~and shall include blanks in which all of the following information must be disclosed:~~]

(1) Pre-registration is available for public presentations through first class mail (P.O. Box 13084, Austin Texas 78711) or email (tbcj@tdcj.state.tx.us). Pre-registration shall be received by the Board office staff no later than four (4) calendar days prior to the posted meeting date of the presentation. In addition to the information required in subsection (c)(2), pre-registration submissions shall include appropriate contact information (daytime phone number and/or email address) for the individual who is registering to speak.

(2) Registration cards and pre-registration submissions shall disclose:

(A) [~~(1)~~] the name of the person who will make [~~making~~] the presentation;

(B) [~~(2)~~] a statement as to whether the person is being remunerated [~~reimbursed~~] for the presentation[~~,~~] and if so, by whom; and if applicable, the name of the person or entity on whose behalf the presentation will be [~~is~~] made;

(C) [~~(3)~~] a statement as to whether the presenter has registered as a lobbyist in relation [~~relationship~~] to the agenda topic being addressed [~~matter in question~~];

(D) [~~(4)~~] a reference to the agenda topic [~~item,~~] on which [~~that~~] the person wishes to present [~~discuss before the Board~~];

(E) [~~(5)~~] an indication as to whether the presenter will [~~wishes to~~] speak for or against the proposed agenda topic [~~item~~]; and

(F) [~~(6)~~] a statement verifying that all [~~factual~~] information that will [~~to~~] be presented is factual, [~~shall be~~] true and correct to the best of the speaker's knowledge [~~of the speaker~~].

(3) The TBCJ Chairman shall have discretion in setting reasonable limits on the time allocated for public presentations on posted agenda topics. If several persons have registered to address the Board on the same agenda topic, it shall be within the discretion of the Board Chairman to request that those persons select a representative amongst themselves to express such remarks or to limit their presentations to an expression of support for views previously articulated.

(4) The TBCJ Chairman shall provide an opportunity for public presentations to occur prior to the Board taking action on the topic denoted on the presenter's registration card. If a person who is registered to speak on a posted agenda item is not present when called upon, that person's opportunity to speak prior to action being taken on such topic shall be forfeited.

(5) A presenter may submit documentation pertaining to the public presentation to the Board office staff no later than three (3) calendar days prior to the posted meeting date where the presentation is to occur. Such documentation shall then be distributed to the Board. Any documentation submitted after the above-referenced date will not be distributed to the Board until after the presentation. A minimum of 12 copies of any such documentation shall be submitted to the Board office staff or distribution will not occur.

(d) [~~(c)~~] Public comments [~~on non-posted topics~~].

(1) The Board defines its areas of jurisdiction in Board Policy BP-01.01, which is available through [~~at~~] the Board office at the address listed in subsection (c) [~~(d)~~] of this rule [~~section~~], or on the Internet at http://tdcj.state.tx.us/policy/policy-home.htm. Twice a year at the second [~~first~~] and fourth regular [~~regularly~~] called meetings of the Board, [~~which are typically held in January and July,~~] an opportunity shall be provided for public comment on issues that are not part of the Board's posted agenda but are within the Board's jurisdiction [~~of the Board~~]. Special called meetings are not counted toward the requirement of this subsection.

(2) Persons who desire to make public comments to the Board at these meetings shall [~~must~~] provide, on the date of the meeting, a completed registration card to onsite Board office [~~the Board's support~~] staff at least ten (10) minutes prior to the meeting's posted start time. Registration cards shall be made available at the entry to the room [~~place~~] where the Board's scheduled meeting is [~~to be~~] held.

(3) Pre-registration is [~~also~~] available for public comments [~~individuals interested in speaking at the bi-annual public comment periods. Pre-registration must be submitted to the Board office either~~] through first class mail (P.O. Box 13084, Austin Texas 78711) or email (tbcj@tdcj.state.tx.us). [~~,~~] Pre-registration shall be received by Board office staff [~~and must take place~~] no earlier than the first day of the [~~even-numbered~~] month preceding the Board meeting for which the registration is intended[~~,~~] and no later than four (4) [~~seven (7)~~] calendar days prior to the posted [~~same~~] meeting date where the comments are to occur. In addition to the information required in subsection (d)(4), pre-registration submissions shall include appropriate contact information (daytime phone number and/or email address) for the individual who is registering to speak.

(4) Registration cards and pre-registration submissions shall [~~must~~] disclose [~~the following information~~]:

(A) the name of the person who will make [~~making~~] the comments [~~presentation~~];

(B) a statement as to whether the person is being remunerated [~~reimbursed~~] for the comments, [~~presentation,~~] and if so, by whom; and, if applicable, the name of the person or entity on whose behalf the comments will be [~~presentation is~~] made;

(C) a statement as to whether the presenter has registered as a lobbyist in relation [~~relationship~~] to the topic being addressed [~~matter in question~~];

(D) the topic on which the person shall speak and whether the person will speak for or against the topic; and

(E) a statement verifying that all [~~factual~~] information that will [~~to~~] be presented is [~~shall be~~] factual, true and correct to the best of the speaker's knowledge [~~of the speaker~~].

[~~(d) Requests that issues be placed on an agenda. Persons outside the agency who wish to have an agenda item posted for discussion shall address their request to the Chairman, Texas Board of Criminal Justice, P.O. Box 13084, Austin, Texas 78711. Such requests should be submitted by the first day of the even-numbered month preceding the Board meeting for which the request is intended and are subject to the requirements of the registration card in subsection (b) of this section. The decision whether to calendar a matter for discussion before the full Board, a Board committee, a Board liaison, or with a designated staff member, shall be within the discretion of the Chairman.~~]

(5) [~~(e) Presentation timing.~~] The TBCJ Chairman [~~of the TBCJ~~] shall have discretion in setting reasonable limits on the time [~~to be~~] allocated for public comments. [~~testimony or public comment.~~] If several persons have registered [~~wish~~] to address the Board on the same topic [~~agenda item~~], it shall be within the discretion of the Board Chairman to request that those persons select a representative amongst themselves to express such comments [~~who wish to address the same side of the issue coordinate their comments~~], or limit their comments to an expression of support for views previously articulated. [~~by persons speaking on the same side of an issue. For public testimony on posted agenda topics, the Chairman shall provide an opportunity for said testimony by a person who has submitted a registration card to occur prior to the Board taking action on the item denoted on the registration card.~~]

(6) Public comments shall be heard just prior to the conclusion of the Board meeting, with deviation from this practice within the discretion of the Board Chairman. If a person who is registered to speak on a non-posted topic is not present when called upon, that person shall be called once more following all other registered speakers. If that person is not present at that time, their opportunity to speak at that meeting shall be forfeited.

(7) Presenters may submit documentation pertaining to the public comments to the Board office staff no later than three (3) calendar days prior to the posted meeting date where the comments are to occur. Such documentation shall then be distributed to the Board. Any documentation submitted after the above-referenced date will not be distributed to the Board until after the comments. A minimum of 12 copies of any such documentation shall be submitted to the Board office staff or distribution will not occur.

(e) [~~(f)~~] Disability accommodations. [~~accommodation.~~] Persons with disabilities who have special communication or accommodation needs and who plan to attend a meeting may contact the Board office at (512) 475-3250. [~~in Austin.~~] Requests for accommodation shall [~~should~~] be made at least two (2) calendar days prior to [~~before~~] a posted meeting. The TBCJ shall [~~department will~~] make every reasonable effort to accommodate these needs.

(f) [~~(g)~~] Conduct and decorum. The Board shall [~~will~~] receive public presentations [~~testimony~~] and [~~public~~] comments as authorized by this rule [~~section~~], subject to the following additional guidelines: [~~.~~]

(1) Due to requirements of the Open Meetings Act, questions [~~Questioning of those making presentations~~] shall only occur on public presentations as defined herein (not as to public comments as defined herein) that are [~~testimony~~] associated with posted agenda topics and they shall be reserved for [~~to~~] Board members and staff recognized by the Board Chairman;

(2) Presentations and comments shall remain pertinent to the issues [~~issue~~] denoted on the registration cards [~~card~~];

(3) A presenter [~~person~~] who is determined by the Board Chairman to be disrupting a meeting shall [~~must~~] immediately cease the disruptive activity or leave the meeting room if ordered to do so by the Board Chairman; and

(4) A presenter [~~person~~] may not assign a portion of his or her allotted presentation time to another speaker.

(g) [~~(h)~~] A presenter [~~person~~] may not carry or possess a prohibited weapon (as defined in Section 46.05, Texas Penal Code), an illegal knife, a club[~~,~~] or a handgun, to include a licensed concealed handgun, during any [~~at a~~] meeting of the Board.

(h) Requests for issues to be placed on an agenda. Persons not employed by or under contract with the Agency who wish to propose an agenda item for discussion on a Board meeting shall address the request in writing to the Chairman, Texas Board of Criminal Justice, P.O. Box 13084, Austin, Texas 78711. Such requests shall be titled, "Proposed Agenda Topic" and shall be submitted no later than the first day of the month preceding the Board meeting for which the request is intended. Such requests are subject to the requirements of the registration card in subsection (c) of this rule. The decision as to whether to calendar a matter for discussion before the Board, a Board committee, a Board liaison or with a designated staff member shall be within the discretion of the Board Chairman. Public presentations on topics placed on a Board agenda, at the request of an individual, shall be in accordance with subsection (c) of this rule.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 25, 2007.

TRD-200702094

Melinda Hoyle Bozarth
General Counsel
Texas Department of Criminal Justice
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 463-0422

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CHAPTER 152. CORRECTIONAL INSTITUTIONS DIVISION

37 TAC §152.33

The Texas Board of Criminal Justice (TBCJ) proposes a new rule, §152.33, Addition to the Estes Unit Capacity.

The purpose of the rule is to provide notice of an increase to the capacity of the Estes Unit.

Charles Marsh, Chief Financial Officer for the Texas Department of Criminal Justice, has determined that for the first five (5) years the rule will be in effect, enforcing or administering the rule will cost the agency $2,594,342.

Mr. Marsh has also determined that, for the first five (5) year period, there will not be an economic impact on persons required to comply with the rule. There will not be an effect on small or micro businesses. The anticipated public benefit, as a result of enforcing the rule, will be to increase capacity at correctional facilities.

Comments should be directed to Melinda Hoyle Bozarth, General Counsel, Texas Department of Criminal Justice, P.O. Box 13084, Austin, Texas 78711, Melinda.Bozarth@tdcj.state.tx.us. Written comments from the general public should be received within 30 days of the publication of this rule.

The new rule is proposed under Texas Government Code, §§499.102, 499.104, and 499.105.

Cross Reference to Statutes: Texas Government Code, §§499.103, 499.106, 499.107.

§152.33 Addition to the Estes Unit Capacity.

At the Estes Unit, an additional 40 beds shall increase the capacity to 1,040.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 25, 2007.

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Melinda Hoyle Bozarth
General Counsel
Texas Department of Criminal Justice
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 463-0422

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37 TAC §152.35

The Texas Board of Criminal Justice (TBCJ) proposes a new rule, §152.35, Addition to the Bartlett State Jail Capacity.

The purpose of the rule is to provide notice of an increase to the capacity of the Bartlett State Jail.

Charles Marsh, Chief Financial Officer for the Texas Department of Criminal Justice, has determined that for the first five (5) years the rule will be in effect, enforcing or administering the rule will cost the agency $3,067,859.

Mr. Marsh has also determined that, for the first five (5) year period, there will not be an economic impact on persons required to comply with the rule. There will not be an effect on small or micro businesses. The anticipated public benefit, as a result of enforcing the rule, will be to increase capacity at correctional facilities.

Comments should be directed to Melinda Hoyle Bozarth, General Counsel, Texas Department of Criminal Justice, P.O. Box 13084, Austin, Texas 78711, Melinda.Bozarth@tdcj.state.tx.us. Written comments from the general public should be received within 30 days of the publication of this rule.

The new rule is proposed under Texas Government Code, §§499.102, 499.104, and 499.105.

Cross Reference to Statutes: Texas Government Code, §§499.103, 499.106, 499.107.

§152.35. Addition to the Bartlett State Jail Capacity.

At the Bartlett State Jail, an additional 48 beds shall increase the capacity to 1,049.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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Melinda Hoyle Bozarth
General Counsel
Texas Department of Criminal Justice
Earliest possible date of adoption: July 15, 2007
For further information, please call: (512) 463-0422

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CHAPTER 163. COMMUNITY JUSTICE ASSISTANCE DIVISION STANDARDS

37 TAC §163.35

The Texas Board of Criminal Justice (TBCJ) proposes amendments to §163.35, Supervision. The proposed amendments are necessary to add clarity.

Charles Marsh, Chief Financial Officer for the Texas Department of Criminal Justice (TDCJ), has determined that for the first five (5) years the rule will be in effect, enforcing or administering the rule will not have foreseeable implications related to costs or revenues for state or local government.

Mr. Marsh has also determined that, for the first five (5) year period, there will not be an economic impact on persons required to comply with the rule. There will not be an effect on small or micro businesses. The anticipated public benefit, as a result of enforcing the rule, will be to ensure the proper supervision of offenders on community supervision.

Comments should be directed to Melinda Hoyle Bozarth, General Counsel, Texas Department of Criminal Justice, P.O. Box 13084, Austin, Texas 78711, Melinda.Bozarth@tdcj.state.tx.us. Written comments from the general public should be received within 30 days of the publication of this rule.

The amendments are proposed under Texas Government Code, §509.003.

Cross Reference to Statutes: Texas Government Code, §509.003.

§163.35. Supervision.

(a) Definitions. The following words and terms, when used in this section, shall be defined as follows and apply to both felonies and misdemeanors, unless the context clearly indicates otherwise.

(1) Case-An offender assigned to a community supervision officer (CSO) [~~CSO~~] for supervision.

(2) Direct Supervision-Offenders who are legally on community supervision and who work or reside in the jurisdiction in which they are being supervised and receive a minimum of one (1) face-to-face contact with a CSO every three (3) months. Direct supervision begins at the time of initial face-to-face contact with an eligible CSO. Local Community Supervision and Corrections Departments (CSCDs) [~~CSCDs~~] may maintain direct supervision of offenders living and/or working in adjoining jurisdictions if the CSCD has documented approval from the adjoining jurisdictions.

(3) Face-to-face Contact-A CSO communicates in person with the offender.

(4) Field Visit-A CSO communicates in person with the offender at the offender's place of residence or at another location outside the CSCD office.

(5) Indirect Supervision-Maintenance of a file and/or record of an offender under supervision who meets one (1) of the following criteria:

(A) an offender who neither resides nor works within the jurisdiction of the CSCD and who receives the supervision in other jurisdictions;

(B) an offender who neither resides nor works within the jurisdiction but continues to submit written reports on a monthly basis because the offender [~~he~~] is ineligible or unacceptable for supervision in another jurisdiction;

(C) an offender who has absconded or who has not contacted the [~~his~~] CSO in person within three (3) months;

(D) an offender who resides or works in the jurisdiction, but who, while in compliance with the orders of the court, [~~nevertheless~~] does not meet the criteria for direct supervision; or

(E) an offender [~~offenders~~] who resides [~~reside~~] and works [~~work~~] outside the jurisdiction but reports [~~report~~] in person and who does [~~do~~] not fall under paragraph (2) of this subsection.

(b) System of Offender Supervision. The CSCD directors shall develop a system of offender supervision that is based upon, but not limited to:

(1) the jurisdiction's profile of revoked offenders;

(2) the jurisdiction's profile of offenders under direct community supervision;

(3) the offender's identified risk and needs;

(4) availability of sanctions, programs, services [~~,~~] and community resources;

(5) applicable law and Texas Department of Criminal Justice- Community Justice Assistance Division (TDCJ-CJAD) [~~TDCJ-CJAD~~] standards and policies [~~policy~~]; and

(6) policies of the local judiciary.

(c) Supervision Process. CSOs shall provide direct supervision for cases to include, but not be limited to, the following tasks;[~~,~~]

(1) Orientation/Intake. An orientation/intake session with the offender shall be conducted after the court has placed the offender [~~defendant~~] under supervision. This session shall include a thorough discussion of the conditions of community supervision and terms of release. The CSO shall determine that the offender has received a copy of the conditions of community supervision or terms of release ordered by the court as provided by law.

(2) Assessments. An assessment process that gathers relevant and valid information shall be completed on every offender. This process shall specifically address the offender's risk factors, need areas, obstacles to meeting those needs, offender strengths[~~,~~] and offender resources. The CSO shall request specialized assessments for offenders when it is determined that alcohol or drug abuse contributed to the offense and pursue specialized evaluations when they would significantly assist in the development of appropriate supervision plans for special needs offenders.

(3) Case Classification. Within two (2) months of the date of community supervision placement, acceptance of a transfer case[~~,~~] or discharge from any residential facility, jail [~~,~~] or institution, the CSO shall complete an approved TDCJ-CJAD case classification instrument to assist in the evaluation of the degree of supervision needed by each individual based on the offender's risk and/or needs. Within ten (10) working days of the date of an offender's admission to a Community Corrections Facility (CCF), the CSO assigned to supervise the offender in the facility shall complete the TDCJ-CJAD case classification/assessment instrument.

(4) Strategies for Case Supervision (SCS) Assessments. Within two (2) months of the date of community supervision placement, acceptance of a transfer case[~~,~~] or discharge from any residential facility, jail[~~,~~] or institution, the CSO shall conduct a SCS assessment on each felony offender classified as maximum on case classification, unless a SCS was previously completed. While the SCS assessment may be a useful case management tool, it is not required for offenders during participation in residential programs.

(5) Case Supervision or Treatment Plan. Within two (2) months of the date of the most recent community supervision placement, acceptance of a transfer case[~~,~~] or discharge from any residential facility, the CSO shall develop a written individualized case supervision or treatment plan based on the offender's risk and need factors to address specific problem areas and assist the offender to achieve responsible behavior. The supervision or treatment plan shall be completed within ten (10) working days from the date of an offender's admission to a CCF.

(6) Reassessments. CSOs shall reevaluate risk and need factors and supervision plans at least every 12 months for all direct cases. An approved TDCJ-CJAD reassessment shall be completed any time a significant change occurs in the status of the offender. Any necessary modification of the supervision plan shall be indicated in writing in the case file. Upon discharge from a residential facility, the CSO assigned to supervise the offender in the facility shall complete a discharge plan.

(7) Supervision Contacts. CSOs shall make face-to-face, field visit, telephone[~~,~~] and collateral contacts with the offender, family, community resources[~~,~~] or other persons pursuant to and consistent with a supervision plan and the level of supervision on which the offender is being supervised. Each CSCD director shall establish supervision contact and casework standards at a level appropriate for that jurisdiction, but in all cases, offenders at increased levels of supervision because of assessments of greater risk or special needs shall receive a

higher level of contacts than offenders at lower levels of supervision. The nature and extent for supervision contacts with offenders shall be specified in the CSCD's written policies and procedures.

(8) Documentation in Supervision Case Files. CSOs shall use a problem oriented record keeping system to document all significant actions, decisions, services rendered[,] and periodic evaluations in the offender's case file, including, but not limited to, the offender's status regarding the level of supervision, compliance with the conditions of community supervision, progress with the supervision plan[,] and responses to intervention.

(9) Violations. CSCD directors shall work in conjunction with the local judiciary to specify written policies and procedures under Texas Code of Criminal Procedure, art. 42.12, §10 wherein the CSOs may make recommendations to the courts regarding violations of conditions of community supervision, as well as when violations may be handled administratively. The availability of progressive interventions and [the continuum of] sanctions as [or] alternatives [alternative] to incarceration and incentives shall be considered by the CSO and recommended to the court in eligible cases as determined appropriate by the jurisdiction.

(10) Intrastate Transfers. The standards strive to ensure public safety by recognizing the need of the sending and receiving jurisdictions to continue control and supervision over these offenders.

(A) Except in cases of non-CSCD residential facility placements, supervision shall be transferred if an offender meeting the definition of direct supervision will be in another jurisdiction for more than 30 days, except when the designated representatives of the two (2) CSCDs agree there is good cause for the original jurisdiction to maintain supervision. Only the court retaining jurisdiction over an offender [a defendant] has the authority to modify or alter a condition of community supervision. The CSCD directors shall ensure that CSOs [community supervision officers] providing direct supervision to offenders transferred from other Texas jurisdictions shall fully enforce the order of the court that placed an individual on community supervision. It is the responsibility of the offender to comply with the conditions of community supervision as imposed by the court. The CSCD directors shall ensure that CSOs [community supervision officers] provide the same level of supervision to courtesy cases as they do for the offenders in their jurisdiction. The documents necessary for transfer shall include, [only] the transfer form, the court order placing the offender [person] on community supervision citing all conditions of community supervision, the offense report, criminal history, state identification (SID) and/or personal identifier (PID) [TRN and SID]number (within 90 days of transfer to the receiving jurisdiction), the pre/post-sentence investigation report where legally mandated[,] and any assessments that have been completed. The CSCD directors who decline or cease to provide courtesy supervision to offenders from other jurisdictions shall immediately notify, in writing, the original jurisdiction of the reasons for declining or closing supervision.

(B) Dual Supervision: The court retaining jurisdiction over an offender [a defendant] may also order the offender [defendant] to report to the original jurisdiction as well as the jurisdiction where offender [defendant] resides and/or works.

(11) Transporting Offenders. CSOs shall not transport offenders held in a county jail pursuant to an arrest warrant. All other transportation of offenders shall be in accordance with the CSCD's policies and/or pursuant to a court order.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on May 25, 2007.

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Melinda Hoyle Bozarth
General Counsel
Texas Department of Criminal Justice
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For further information, please call: (512) 463-0422

37 TAC §163.42

The Texas Board of Criminal Justice (TBCJ) proposes amendments to §163.42, Substantial Noncompliance. The proposed amendments are necessary to clarify and revise the definition of substantial noncompliance as it applies to the Texas Department of Criminal Justice-Community Justice Assistance Division (TDCJ-CJAD) standards.

Charles Marsh, Chief Financial Officer for the Texas Department of Criminal Justice, has determined that for the first five (5) years the rule will be in effect, enforcing or administering the rule will not have foreseeable implications related to costs or revenues for state or local government.

Mr. Marsh has also determined that, for the first five (5) year period, there will not be an economic impact on persons required to comply with the rule. There will not be an effect on small or micro businesses. The anticipated public benefit, as a result of enforcing the rule, will be to increase accountability of the Community Supervision and Corrections Departments.

Comments should be directed to Melinda Hoyle Bozarth, General Counsel, Texas Department of Criminal Justice, P.O. Box 13084, Austin, Texas 78711, Melinda.Bozarth@tdcj.state.tx.us. Written comments from the general public should be received within 30 days of the publication of this rule.

The amendments are proposed under Texas Government Code, §509.012.

Cross Reference to Statutes: Texas Government Code, §509.003 through 509.006; Texas Government Code, Chapter 551 and Texas Local Government Code §140.004.

§163.42. Substantial Noncompliance.

(a) Definition. Substantial noncompliance with the Texas Department of Criminal Justice-Community Justice Assistance Division (TDCJ-CJAD) [TDCJ-CJAD] standards, for purposes of Texas Government Code §509.012, is defined as:

(1) intentional diversion, theft or misapplication of TDCJ-CJAD funding or grants for purposes other than the state funding award or allocation;

(2) violations of laws, regulations or official manuals specific to the operations of the Community Supervision and Corrections Departments (CSCDs) [CSCDs];

(3) intentional refusal to implement a TDCJ-CJAD approved action plan [Action Plans] that is [are] a result of audits, reviews[,] or inspections;

(4) for purposes of qualifying for state aid [by complying with the Open Meetings Act] under §163.43(a)(1)(F) of this title (relating to Funding and Financial Management) by[,] failing to hold the meeting to finalize the CSCD budget as required by Texas Local Government Code §140.004 and [in compliance with] the Texas Open Meetings Act; and

(5) interference, obstruction, or hindrance with any efforts by the State Comptroller, County Auditor of the county that manages the CSCD's funds, TDCJ-CJAD [~~CJAD~~], TDCJ-Internal Audit Division, Legislative Budget Board, Texas State Auditors Office or Texas Sunset Advisory Commission [~~Criminal Justice Policy Council~~], to examine or audit the records, transactions and performance of the [~~subject~~] CSCD or facilities.

(b) Imposing Sanctions. Sanctions imposed for substantial noncompliance shall be in accordance with provisions outlined in §163.47 of this title (relating to Contested Matters).

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

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Melinda Hoyle Bozarth
General Counsel
Texas Department of Criminal Justice
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For further information, please call: (512) 463-0422

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WITHDRAWN RULES

Withdrawn Rules include proposed rules and emergency rules. A state agency may specify that a rule is withdrawn immediately or on a later date after filing the notice with the Texas Register. A proposed rule is withdrawn six months after the date of publication of the proposed rule in the Texas Register if a state agency has failed by that time to adopt, adopt as amended, or withdraw the proposed rule. Adopted rules may not be withdrawn. (Government Code, §2001.027)

TITLE 19. EDUCATION

PART 1. TEXAS HIGHER EDUCATION COORDINATING BOARD

CHAPTER 22. GRANT AND SCHOLARSHIP PROGRAMS

SUBCHAPTER B. PROVISIONS FOR THE TUITION EQUALIZATION GRANT PROGRAM

19 TAC §22.24

The Texas Higher Education Coordinating Board withdraws the proposed amendments to §22.24 which appeared in the June 1, 2007, issue of the *Texas Register* (32 TexReg 2967).

Filed with the Office of the Secretary of State on June 1, 2007.

TRD-200702152
Bill Franz
General Counsel
Texas Higher Education Coordinating Board
Effective date: June 1, 2007
For further information, please call: (512) 427-6114

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ADOPTED RULES

Adopted rules include new rules, amendments to existing rules, and repeals of existing rules. A rule adopted by a state agency takes effect 20 days after the date on which it is filed with the Secretary of State unless a later date is required by statute or specified in the the rule (Government Code, §2001.036). If a rule is adopted without change to the text as published in the proposed rule, then the *Texas Register* does not republish the rule text here. If a rule is adopted with change to the text of the proposed rule, then the final rule text is included here. The final rule text will appear in the Texas Administrative Code on the effective date.

TITLE 1. ADMINISTRATION

PART 15. TEXAS HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 355. REIMBURSEMENT RATES

SUBCHAPTER J. PURCHASED HEALTH SERVICES

DIVISION 4. MEDICAID HOSPITAL SERVICES

1 TAC §355.8063

The Health and Human Services Commission (HHSC) adopts an amendment to §355.8063, without changes to the proposed text as published in the April 27, 2007, issue of the *Texas Register* (32 TexReg 2338) and will not be republished. The adopted rule amendment describes the reimbursement methodology for freestanding psychiatric hospitals for inpatient hospital services.

The adopted changes to §355.8063 revise the Medicaid reimbursement methodology for freestanding psychiatric inpatient hospitals. The reimbursement methodology for freestanding psychiatric hospitals will change from Tax Equity and Fiscal Responsibility Act (TEFRA) principles, which is a cost-based reimbursement, to a hospital-specific per diem rate, which will be reimbursed under a prospective payment system (PPS).

HHSC did not receive comments regarding the proposed rule during the 30-day comment period.

The amendment is adopted under the Texas Government Code, §531.033, which provides the Executive Commissioner of HHSC with broad rulemaking authority; the Human Resources Code, §32.021, and the Texas Government Code, §531.021(a), which provide HHSC with the authority to administer the federal medical assistance (Medicaid) program in Texas; and Human Resources Code, §32.028, which gives HHSC the authority to adopt rules governing the determination of rates for the medical assistance program.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702155

Steve Aragón

Chief Counsel

Texas Health and Human Services Commission

Effective date: June 24, 2007

Proposal publication date: April 27, 2007

For further information, please call: (512) 424-6900

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1 TAC §355.8065

The Health and Human Services Commission (HHSC) adopts amendments to §355.8065, without changes to the proposed text as published in the April 27, 2007, issue of the *Texas Register* (32 TexReg 2339) and will not be republished.

The purpose of this adopted amendment is to require children's hospitals to become designated as part of the state's trauma network in order to receive Medicaid disproportionate share hospital (DSH) funds. Until now, children's hospitals were not required to obtain a trauma designation in order to receive DSH funds. The adopted amendment deletes this exception for children's hospitals.

HHSC did not receive comments regarding the proposed rule during the 30-day comment period.

The amendment is adopted under the Texas Government Code, §531.033, which provides the Executive Commissioner of HHSC with broad rulemaking authority; and the Human Resources Code, §32.021, and the Texas Government Code, §531.021(a), which provide HHSC with the authority to administer the federal medical assistance (Medicaid) program in Texas.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702156

Steve Aragón

Chief Counsel

Texas Health and Human Services Commission

Effective date: June 24, 2007

Proposal publication date: April 27, 2007

For further information, please call: (512) 424-6900

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CHAPTER 357. MEDICAL FAIR HEARINGS

SUBCHAPTER I. FORMAL APPEALS

1 TAC §§357.481 - 357.490

The Texas Health and Human Services Commission (HHSC) adopts the repeal of §§357.481 - 357.490, Formal Appeals, without changes to the proposed text as published in the December 29, 2006, issue of the *Texas Register* (31 TexReg 10464) and will not be republished.

These rules are repealed in order that they might be replaced by new Subchapter I, §§357.481 - 357.498, now entitled Hearings Under the Administrative Procedure Act, which is adopted elsewhere in this issue of the *Texas Register*. Their replacement allows for updated procedural rules for parties and administrative law judges of the HHSC Appeals Division which are necessary for the conduct of hearings under the Texas Administrative Procedure Act.

The following rules are being repealed: §357.481, Definitions; §357.482, Computation of Time; §357.483, Venue; §357.484, Notice of Adverse Action; §357.485, Request for a Hearing; §357.486, Notice of Hearing; §357.487, Administrative Law Judge; §357.488, Other Procedures; §357.489, Proposals for Decision, Final Decisions, and Final Orders; and §357.490, Motions for Rehearing.

No comments were received concerning the proposed repeal of these rules.

The repeal is adopted under Government Code, §531.033, which authorizes the executive commissioner of HHSC to adopt rules necessary to carry out the commission's duties.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on May 31, 2007.

TRD-200702130
Steve Aragón
Chief Counsel
Texas Health and Human Services Commission
Effective date: June 20, 2007
Proposal publication date: December 29, 2006
For further information, please call: (512) 424-6900

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CHAPTER 357. HEARINGS
SUBCHAPTER I. HEARINGS UNDER THE ADMINISTRATIVE PROCEDURE ACT

1 TAC §§357.481 - 357.498

The Texas Health and Human Services Commission (HHSC or the Commission) adopts new §§357.481 - 357.498, concerning Hearings Under the Administrative Procedure Act, without changes to the proposed text as published in the December 29, 2006, issue of the *Texas Register* (31 TexReg 10464) and will not be republished.

The purpose of these rules is to provide procedural rules for parties and administrative law judges of the HHSC Appeals Division. These rules are necessary for the conduct of hearings under the Texas Administrative Procedure Act for HHSC and system agencies. The rules in this subchapter conform to Commission practice and fulfill the purpose intended by Government Code, §531.0055, that performance of administrative support services for health and human service agencies, including legal support, is the responsibility of HHSC.

No comments were received concerning the adoption of the new rules.

The new rules are adopted under Texas Government Code, §531.033, which provides the executive commissioner of HHSC with broad rulemaking authority to carry out the Commission's duties.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on May 31, 2007.

TRD-200702131
Steve Aragón
Chief Counsel
Texas Health and Human Services Commission
Effective date: June 20, 2007
Proposal publication date: December 29, 2006
For further information, please call: (512) 424-6900

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TITLE 16. ECONOMIC REGULATION

PART 1. RAILROAD COMMISSION OF TEXAS

CHAPTER 14. REGULATIONS FOR LIQUEFIED NATURAL GAS (LNG)
SUBCHAPTER A. GENERAL APPLICABILITY AND REQUIREMENTS

16 TAC §14.2001

The Railroad Commission of Texas adopts the repeal of §14.2001, relating to LNG Advisory Committee, in conjunction with its notice of review and re-adoption of 16 Texas Administrative Code Chapter 14, pursuant to Texas Government Code, §2001.039; the repeal is adopted without changes from the version published in the April 13, 2007, issue of the *Texas Register* (32 TexReg 2077).

The Commission adopts the repeal of §14.2001 because by the terms of the rule, the LNG advisory committee ceased to exist on August 31, 2006.

The Commission received no comments on the proposed repeal.

The Commission adopts the repeal under Texas Natural Resources Code, §116.012, which authorizes the Commission to adopt rules and standards relating to liquefied natural gas activities to protect the health, welfare, and safety of the general public; and Texas Government Code, Chapter 2110, State Agency Advisory Committees.

Statutory authority: Texas Natural Resources Code, §116.012, and Texas Government Code, Chapter 2110.

Cross-reference to statute: Texas Natural Resources Code, Chapter 116, and Texas Government Code, Chapter 2110.

Issued in Austin, Texas, on May 30, 2007.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on May 30, 2007.

TRD-200702118
Mary Ross McDonald
Managing Director
Railroad Commission of Texas
Effective date: June 19, 2007
Proposal publication date: April 13, 2007
For further information, please call: (512) 475-1295

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CHAPTER 18. UNDERGROUND PIPELINE DAMAGE PREVENTION

16 TAC §§18.1 - 18.12

The Railroad Commission of Texas adopts new §§18.1 - 18.12, relating to Scope, Applicability, and General Provisions; Definitions; Excavator Notice to Notification Center; Excavator Obligation to Avoid Damage to Underground Pipelines; Operator and Excavator Obligations with Respect to Positive Response; General Marking Requirements; Excavator Marking Requirements; Operator Marking Requirements; Options for Managing an Excavation Site in the Vicinity of an Underground Pipeline; Excavation within Tolerance Zone; Reporting Requirements; and Penalty Guidelines, in new Chapter 18, entitled Underground Pipeline Damage Prevention, with changes to the proposed versions published in the December 22, 2006, issue of the *Texas Register* (31 TexReg 10228).

The new rules implement the authority of the Commission under Texas Natural Resources Code, §117.012, and Texas Utilities Code, §121.201 (as amended by House Bill 2161, Acts 2005, 79th Leg., R.S., ch. 267, §§6 and 13, eff. Sept. 1, 2005). As amended, Texas Natural Resources Code, §117.012, provides that the Commission shall adopt rules that include safety standards for and practices applicable to the intrastate transportation of hazardous liquids or carbon dioxide by pipeline and intrastate hazardous liquid or carbon dioxide pipeline facilities, including safety standards related to the prevention of damage to such a facility resulting from the movement of earth by a person in the vicinity of the facility, other than movement by tillage that does not exceed a depth of 16 inches. As amended, Texas Utilities Code, §121.201(a)(1), states that the Commission may by rule prescribe or adopt safety standards for the transportation of gas and for gas pipeline facilities, including safety standards related to the prevention of damage to such a facility resulting from the movement of earth by a person in the vicinity of the facility, other than movement by tillage that does not exceed a depth of 16 inches. Both provisions impose a limitation on the Commission's rulemaking authority by stating that the Commission may not implement rules adopted under the new legislation until September 1, 2007.

In addition, by adopting the new rules in Chapter 18, the Commission is implementing the authority delegated by and under Texas Health and Safety Code, §756.106 (as added by Senate Bill 9, Acts 2005, 79th Leg., R. S., ch. 1337, §19, and editorially renumbered as Health and Safety Code, §756.126). This provision states that the Commission shall adopt and enforce safety standards and best practices, including those described by 49 U.S.C. §6105 *et seq*., relating to the prevention of damage by a person to a facility under the jurisdiction of the Commission. This legislation requires the Commission to adopt the safety standards and best practices required by Health and Safety Code, §756.126, not later than June 1, 2007. The new rules in Chapter 18, with some stated exceptions, would apply to all persons engaged in or preparing to engage in the movement of earth in the vicinity of an intrastate underground pipeline containing flammable, toxic, or corrosive gas, a hazardous liquid, or carbon dioxide. However, Texas Natural Resources Code, §117.012, and Texas Utilities Code, §121.201, specifically authorize the Commission to exempt other entities or occupations if the Commission determines in its rulemaking process that exempting those entities or occupations from the rules is either in the public interest or not likely to cause harm to the safety and welfare of the public. In the proposal preamble, the Commission gave notice that one result of this rulemaking may be the exemption of additional entities and/or activities from the new rules in Chapter 18.

Although there are some specific requirements for both excavators and pipeline operators set forth in the proposed new rules, generally the Commission attempted to avoid provisions that would either duplicate or contradict the mandates of Texas Utilities Code, Chapter 251, the Underground Facility Damage Prevention and Safety Act. The requirements in the new rules are based on the presumption that an excavator will notify a notification center pursuant to, and that a pipeline operator will respond in accordance with, the provisions of Texas Utilities Code, Chapter 251, and the requirements of the notification center. However, compliance with the provisions of Texas Utilities Code, Chapter 251, and the requirements of a notification center does not necessarily constitute compliance with the requirements of this chapter.

The Commission received comments from the following groups or associations, companies, and individuals: AGC of Texas; Air Products; American Petroleum Institute and the Association of Oil Pipe Lines ("API and AOPL"); Atmos Energy Corporation ("Atmos"); CenterPoint Energy Arkla, CenterPoint Energy Entex, and CenterPoint Energy Intrastate Pipelines, Inc. (CEIP) (collectively "CenterPoint"); Common Ground Alliance ("CGA"); CoServ Gas ("CoServ"); Gary W. Craig; Devon Energy Corporation ("Devon"); Equistar Chemicals LP ("Equistar"); Kinder Morgan Texas Pipeline, L.P., Kinder Morgan Tejas Pipeline, L.P., Kinder Morgan Border Pipeline, L.P., and Kinder Morgan North Texas Pipeline, L.P. (collectively "Kinder Morgan"); Marathon Pipe Line ("Marathon"); Occidental Permian Ltd., OXY USA WTP LP, and OXY USA, Inc. (collectively "OXY"); the Danielle Dawn Smalley Foundation ("Smalley Foundation"); SM&P Utility Resources, Inc. ("SM&P"); Texas Department of Transportation ("TxDOT"); Texas Gas Association ("TGA"); Texas Gas Service Company ("TGS"); Texas Oil & Gas Association ("TxOGA"); Texas Pipeline Association ("TPA"); Texas Pipeline Safety Coalition ("the Coalition"); the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration ("PHMSA"); and West Texas Gas, Inc. and WTG Gas Transmission Company (collectively "WTG"). Most comments supported the Commission's efforts to improve pipeline safety, but all sought clarification or made suggestions for changes. The comments are addressed in detail in the following paragraphs.

CGA, on behalf of its Board of Directors and more than 1,400 members, congratulated the Railroad Commission of Texas on its proposed new rules in Chapter 18, Underground Pipeline Damage Prevention. CGA noted that many of the proposed rules are similar to the practices contained in "The Common Ground Alliance Best Practices, Version 3.0." The initial Best Practices have been in existence since the initial Common Ground Study report of 1999. A number of new practices have been added in

the intervening years. These Best Practices were developed on a consensus basis by all 15 stakeholder groups of the CGA. CGA noted that a description and examples of each of these practices are included in the Best Practices and can be found on its website at www.commongroundalliance.com.

CGA noted that a large number of its members and sponsors reside in Texas, and was glad to see their home state moving in a direction proposed by these members as a national direction. The CGA is an Association of 15 different stakeholder groups representing all parties that are dedicated to a "Shared Responsibility in Damage Prevention to our Underground Infrastructure." The Commission thanks CGA for its support of the proposed new rules.

AGC of Texas was an active participant in the stakeholder process to develop the rules in this chapter and found the experience positive and most beneficial, and thanked Mary McDaniel and her staff for their willingness to work with AGC of Texas to address its concerns during the stakeholder meetings and the staff's efforts to prepare a rule package that is fair and balanced. The Commission thanks AGC of Texas for its participation in the workshops and for its comments on the proposed rules.

Equistar appreciated the opportunity to review and comment on the proposed rules and greatly supports the Commission's efforts to strengthen rules and enforcement regarding the protection of underground pipelines. Overall, the proposed additions will create a step change improvement in collective efforts to reduce third-party damage. The Commission thanks Equistar for its comments on the proposed rules.

Kinder Morgan appreciated the opportunity to provide comments to the Commission on the proposed new rules. The combined assets of Kinder Morgan consist of almost 6,000 miles of natural gas pipelines. Kinder Morgan is committed to operating safe natural gas pipeline facilities and providing reliable service to the citizens of the State of Texas. Accordingly, Kinder Morgan will be affected by the new rules in Chapter 18. Kinder Morgan also appreciates the efforts of the Commission staff for the time spent ensuring a deliberate open process in which the rules were developed. Overall, Kinder Morgan stated, the rules are a great first step toward improving pipeline safety and meeting the requirements of the recent and past Pipeline Safety Acts and the spirit of the Common Ground Alliance Best Practices. Kinder Morgan stated its agreement with and support of the comments filed by TPA and the Coalition in this proceeding. These organizations have developed a number of recommendations and suggestions that will clarify several provisions of the new rules in addition to addressing concerns relating to the penalty rule. Kinder Morgan urged the Commission to revise the proposed rules in accordance with those comments. Kinder Morgan looks forward to working with the Commission as the implementation of the damage prevention rule occurs. The Commission thanks Kinder Morgan for its participation in the workshops and for its comments on the proposed rules.

Marathon operates approximately 220 miles of pipeline on the Outer Continental Shelf (OCS). Marathon supports the Railroad Commission of Texas in its effort for constant improvement of the underground pipeline damage prevention regulations. The Commission thanks Marathon for its comments on the rules.

The WTG natural gas utilities operate hundreds of miles of transmission and distribution pipelines within the State of Texas. WTG commented that the proposed new rules will impact its business operations, affect the cost of daily business operations, and, to the extent the rules increases their costs of doing business, will ultimately increase rates it charges the consumers served by WTG.

WTG acknowledged the tremendous amount of work done by the Pipeline Safety Division and others who have contributed their time and effort in helping develop the rules with the end being to create safer operating conditions for pipelines under the jurisdiction of the Commission.

The Commission thanks WTG for its comments, but disagrees that the new rules will necessarily increase the cost of doing business. The Commission points out that damage to pipelines also imposes costs for mounting an emergency response, managing the disruption, and repairing the line, in addition to loss of revenue because of loss of service to customers. Preventing that damage is a prudent business practice.

API and AOPL represent hazardous liquids pipeline operators in the United States that own or operate approximately 85 percent of the nation's hazardous liquid pipeline capacity. More miles of pipeline cross Texas than any other state, and API and AOPL believed it imperative that the pipelines serving our nation's energy needs be better protected from excavation damage. API and AOPL support the intent and objectives of the proposed new rules and also support the comments of the Coalition. API and AOPL also made comments on specific portions of the proposed new rules. API and AOPL welcomed the new rules as a fair measure designed in a manner that advances the efforts of many pipeline industry stakeholders to reduce, if not eliminate, incidents of third-party damage to underground pipelines. The new rules may be expected to enhance awareness and communications among the various parties involved in excavation and pipeline operations, as well as to provide the means and incentives for such parties to conduct their activities in a manner that protects against pipeline damage. API and AOPL encouraged timely implementation of the rules upon promulgation. API and AOPL reviewed the comments of the Coalition, concur in and support those comments, and encourage the Commission to give weighty consideration to them. The Commission thanks API and AOPL for their participation in the rulemaking process, and for their support of the Commission's efforts to improve pipeline safety in Texas.

Atmos is the nation's largest pure natural gas utility with operations in twelve states. Atmos's Texas operations provide dependable, safe natural gas service to 516 municipalities and more than 1.8 million customers. Atmos applauds the efforts of the Commission in holding workshops on damage prevention and seeking input from both excavators and operators in developing these proposed rules. The Commission thanks Atmos for its participation in the rulemaking process, and for its support of the Commission's efforts to improve pipeline safety in Texas.

SM&P provides underground locating services throughout the State of Texas, including natural gas lines. SM&P has been dedicated to increasing the level of safety within the locating industry as a whole and is committed to ensuring the best possible levels of public safety and infrastructure protection in the industry. SM&P fully supports the Commission's endeavors to maximize public safety and the intent behind the proposed new rules and acknowledges the Commission's work and efforts in creating the proposed new rules. However, SM&P believed that, as written, the proposed new rules will have unintended consequences and therefore should not be implemented in their current form. The Commission thanks SM&P for its comments, but does not agree that the rules should not be implemented in their current form and

notes that the rules as adopted are slightly different from the proposed versions because they incorporate clarifying changes.

TxOGA appreciated the opportunity to submit comments concerning the proposed new rules. TxOGA supports the Commission's efforts in holding public meetings to receive suggestions and comments and in drafting the proposal, and offered some additional recommendations and observations for consideration.

TxOGA is a statewide association with over 2000 members representing all facets of the oil and gas industry from exploration and production to transportation/pipeline to refining and marketing, including both major and independent companies. TxOGA thanked the Commission and its staff for developing a damage prevention rule that will assist in implementing safety standards for any movement of earth deeper than 16 inches near a pipeline facility. Damage prevention is a top priority for the pipeline industry in Texas and TxOGA appreciated the opportunity to work with other stakeholders and the Commission to advance a comprehensive program in Texas that will meet the requirements of the Pipeline Safety Act of 2002 and Pipeline Inspection, Protection, and Enforcement Act of 2006.

TxOGA supports the damage prevention concepts outlined in the CGA Best Practices, and those discussed throughout the rule development process. TxOGA members understand that a comprehensive damage prevention effort will take time to be fully implemented, and on-going changes may be warranted in order to adjust problematic provisions. The Commission thanks TxOGA for its participation in the rulemaking process and for its comments and agrees that there will be a need to review the effectiveness of the rules in reducing damage to underground pipelines.

The CenterPoint companies are operators of gas pipeline systems registered with the Commission. CenterPoint Energy Arkla and CenterPoint Energy Entex are local distribution companies engaging in intrastate natural gas sales to and natural gas transportation for more than 1,481,470 residential, commercial, and industrial customers in the State of Texas. CEIP operates approximately 240 miles of transmission pipelines serving 120 customers in Texas.

In general, CenterPoint supports the new rules because they would improve compliance with the Texas One Call Law (Texas Utilities Code, Chapter 251) and create a helpful regulatory scheme governing the marking of a pipeline after an excavator calls the Texas one call system. In order to accomplish these goals, CenterPoint commented, the rules must also provide certainty and consistency in enforcement. In addition and as recognized in the preamble to the proposed rules, they also should conflict as little as possible with the Texas One Call Law. CenterPoint believed that the proposed rules largely accomplish these objectives, but also that they can be improved in certain areas. The Commission thanks CenterPoint for its comments and agrees that the changes made in the adopted rules, some of which were suggested by CenterPoint, clarify and improve the rules.

CoServ's comments noted that it is situated in one of the fastest growing areas in the state, the Dallas-Fort Worth Metroplex. As a result of intense construction activity, CoServ sustains a disproportionately large number of cut lines every year. Last year, CoServ grew from 40,000 customers to 50,000, and during this time its infrastructure was damaged 255 times by third parties. Excavation damage is CoServ's number one safety concern, and it has been very supportive of efforts to strengthen damage prevention laws and regulation. CoServ has taken additional steps on its own initiative to ensure public safety, such as voluntarily installing excess flow valves, being an active member of the North Texas Damage Prevention Council, and sponsoring excavator safety training sessions with Texas Excavation Safety Systems.

CoServ applauded the hard work on the part of the Commission staff in producing the proposed rules, and wholeheartedly supports the intent of the proposed new rules; once implemented, CoServ pledged to work hard to ensure their success. Nevertheless, CoServ commented, that, as written, some provisions would have unintended consequences. For example, requiring utilities to report *all* damage to the Commission will probably reduce the current number of damage reports by excavators for fear of being fined by the Commission. Further, CoServ observed, the proposal's broad new reporting and requirements are likely to swamp the Commission with more information than it can handle, even with the planned additional resources. For example, the Commission estimates it will receive 1,000 damage reports under the new rules; however, last year CoServ alone sustained over 250 damage incidents, which is one-fourth of the Commission's estimate. CoServ's comments recommended an alternate reporting program intended to accomplish the same result.

CoServ conceded that the problems the Commission identified are real, and CoServ supports efforts to address them. However, CoServ stated that many of the proposed solutions could be improved by adopting the CGA Best Practices. CGA is a non-profit organization dedicated to promoting damage prevention; its Best Practices program brought together stakeholders, including utilities, excavators, and regulators, to look at all aspects of damage prevention practices. CoServ Gas is a member of CGA, and its comments substituted a number of the Commission's proposed solutions with CGA Best Practices, which CoServ believed is an effective solution and uses a well-recognized authority.

CoServ also commented on the need to educate homeowners, municipalities, and TxDOT regarding the new rules. Currently pipeline companies have the task of educating the affected public and their customers under RP1162. The proposed rules are a huge change for the industry, on top of the fact that many entities have been exempt under the current law for many years. CoServ commented that there must be a reasonable period of time to educate those impacted by the changes. For example, under the current law, homeowners who are hand digging are not required to call for locates. CoServ noted that the proposed rules do not exclude tillage of a depth over 16 inches, which would require homeowners to call for locates when they are planting bushes or trees at a depth that exceeds 16 inches. In CoServ's view, a reasonable amount time needs to be spent educating entities that were previously exempt.

The Commission thanks CoServ for its comments and its support of efforts to improve underground pipeline safety standards. The Commission acknowledges the value of the CGA Best Practices; in fact, they were the foundation of the proposed new rules in Chapter 18. The Commission recognizes also that these new rules are a first step in what is necessarily an ongoing effort to ensure pipeline safety to the extent possible. The Commission disagrees that it will be swamped with information that it cannot handle; part of the intent is to be able to gather and evaluate information about pipeline damage incidents to guide the development of standards for excavating in the vicinity of underground pipelines. The Commission points out that if it is swamped with more information than it can handle, the Commission can re-

vise the rules regarding reporting of damage incidents. Finally, the Commission has declined to require that pipelines conduct mandatory public education specifically focused on one call issues and instead to adopt the federal requirements for public education in API 1162.

The Danielle Dawn Smalley Foundation is a nonprofit corporation established in 2002 to promote pipeline safety and pipeline safety education to excavators, first responders, civic and community groups, and school systems. The Smalley Foundation believes that the best results can be achieved through innovative collaborations between non-profits, governmental and educational entities, and private industry. The Foundation is apolitical but certainly supportive of reasonable measures designed to enhance pipeline safety. In reviewing the proposed new rules in Chapter 18, the Foundation concluded that the new rules will result in a safer public. The Commission thanks the Smalley Foundation for its comments and its support of pipeline safety efforts.

Devon appreciated the opportunity to review and comment on the proposed rules. Devon subsidiaries that operate pipelines in Texas are Acacia Natural Gas Corporation, Devon Energy Production Company, L.P., Devon Field Services Company, Devon Gas Services, L.P, and Southwestern Gas Pipeline, Inc. Devon supports the Commission's efforts to protect underground pipelines, improve public safety, and allow for operators and excavators to agree on special protocols for large projects. These options should encourage cooperation, reduce third-party damage, and better protect the public. Devon offered comments on specific provisions in the rules to further develop and clarify the rules to enhance these efforts.

TxDOT commented that the proposed new rules in new Chapter 18 exceed the Commission's authority by attempting to regulate TxDOT's operation of the state highway system. TxDOT stated that the preamble to the proposed rules erroneously states that Health and Safety Code, Subchapter H, authorizes the Commission to regulate the activities of anyone who moves earth in the vicinity of an intrastate underground pipeline. TxDOT's opinion is that Subchapter H applies only to excavations on easements or rights of way *owned by* a pipeline company. Most pipelines on the highway right-of-way are installed not pursuant to any pipeline easement or right-of-way, but as authorized by the Texas Utilities Code, §181.042, on an at-risk basis on property owned and controlled exclusively by TxDOT. Subchapter H does not apply to these pipelines.

TxDOT commented that the other two statutes referenced as authority for the Commission to adopt these rules are Texas Utilities Code, §121.201, and Natural Resources Code, §117.012, each of which authorizes the Commission to exempt TxDOT from the rules. TxDOT urged the Commission to do so in order to preserve the ability of pipeline companies to continue to use the highway right-of-way.

TxDOT argues that the Texas Utilities Code grants gas companies the right to place their pipelines on highway right-of-way, but grants them no property interest. Under Texas law, this right to use the highway right-of-way is not absolute, but must always be subordinate to the use of the property for highway purposes. In *City of San Antonio v. Bexar Metro. Water Dist.*, 309 S.W.2d 491, 492 (Tex. Civ. App.-San Antonio 1958, *writ ref'd*), the court stated, "The main purposes of roads and streets are for travel and transportation, and while public utilities may use such roads and streets for the laying of their telegraph, telephone, and water lines, and for other purposes, such uses are subservient to the main uses and purposes of such roads and streets." See also *City of San Antonio v. United Gas Pipe Line Co.*, 388 S.W.2d 231, 234 (Tex. Civ. App.-San Antonio 1965, *writ ref'd n.r.e.*). "The primary purpose for which highways and streets are established and maintained is for the convenience of public travel. The use (of) such highways and streets for water mains, gas pipes, telephone and telegraph lines is secondary and subordinate to the primary use for travel, and such secondary use is permissible only when not inconsistent with the primary object of the establishment of such ways." In 2002, the Attorney General reiterated TxDOT's authority to regulate utilities on the right-of-way in Opinion No. GA-0003. By placing strict regulations on land use to the extent that TxDOT no longer controls the operation of its own roadways, TxDOT claims that the Commission is creating a situation whereby the presence of gas lines is inconsistent with the use of the roadways for travel. In TxDOT's view, this negates the provisions of Utilities Code, §181.042, and would necessitate the removal of the lines from the highway right-of-way.

TxDOT pointed out that new rule §18.1(a) applies to excavation "in the vicinity of an underground pipeline containing flammable, toxic, or corrosive gas, a hazardous liquid, or carbon dioxide," but that the term "in the vicinity" is not defined. Moreover, because the presence of some types of subject pipelines may not be reasonably known by an excavator prior to issuance of a one call notification, excavators would be required to treat every excavation deeper than 16 inches within the highway right-of-way as though it were covered by the rule.

TxDOT commented generally that the Commission has elected to ensure the safety of underground pipelines using the existing Texas One Call procedures while other means of protecting pipelines (i.e., design standards, etc.) would achieve the same results without either encroaching on the authority of or unnecessarily burdening other agencies, including the Texas One Call Board as well as TxDOT.

TxDOT asserted that the new rules will result in costs of $22.9 million annually for TxDOT, for maintenance operations alone, and that an estimated annual cost of $108.9 million will be required by utility companies required to respond through the One Call system to the approximately 382,000 additional calls TxDOT will make to comply with the new rules. Again, TxDOT pointed out that these costs are associated with its maintenance operations only. TxDOT stated that costs to its archeology program are more difficult to identify with confidence, as there are many intangible variables. For example, existing contracts would have to be voided or renegotiated, time periods necessary to obtain NEPA and NHPA clearance would be extended, and procedures for planning and executing field surveys would have to be revamped. However, because the rules would require field surveys to include a minimum of two trips rather than one, a minimum cost estimate for this program alone can be obtained by doubling average annual survey costs, which are averaging $598,000.00 per year over the last three years. Actual costs would probably be considerably higher.

TxDOT concluded that the new rules, as proposed, would extremely hamper, delay, and restrict the ability of TxDOT to work within the highway right-of-way to protect the safety of our traveling public. The proposed rules would impose delays, not only on highway construction projects but, even more importantly, on standard safety procedures, creating unnecessary hazards for the traveling public. As noted above, TxDOT was previously provided an exemption by the Legislature within Section 251.004 of the Texas Utilities Code to address this safety issue. The rules,

as proposed, appear to nullify this exemption, placing the traveling public at significant risk of injury or death. TxDOT strongly recommended exempting TxDOT activities from these proposed rules through Section 251.004 of the Texas Utilities Code.

The Commission disagrees with TxDOT that the preamble expressly asserts authority to regulate TxDOT pursuant to Health and Safety Code, Subchapter H. The Commission finds, however, that pursuant to Texas Utilities Code, §121.201, and Natural Resources Code, §117.012, the Commission has the authority to require excavators and operators to comply with the safety requirements set forth in Texas Health & Safety Code, Subchapter H, relating to Construction Affecting Pipeline Easements and Rights-of-Way. Further, the provisions of Texas Utilities Code, §121.201, and Natural Resources Code, §117.012, authorize, but do not require, the Commission to exempt from the rules "other entities or occupations if the Commission determines in its rulemaking process that exempting those entities or occupations . . . is in the public interest or is not likely to cause harm to the safety and welfare of the public." The Commission recognizes the exemption that TxDOT holds pursuant to Texas Utilities Code, §251.004, but notes that the Commission has no authority or obligation to enforce any of the provisions of that statute.

The Commission also notes, however, that TxDOT and its contractors have been making calls to the notification centers, even though it is not required to do so under Texas Utilities Code, §251.004. Knowing that TxDOT was already using the notification centers to request pipeline locates was part of the basis of the Commission's fiscal note. Regardless of the number of incidents or the ability to find "fault," the Commission's goal is to promote safety and to align Texas practices with national best practices for excavating in the vicinity of underground pipelines. The Commission is committed to adopting improved safety practices that will prevent costly damage to underground pipelines and possible personal injury or loss of life. The Commission disagrees that design standards would achieve the same results in terms of preventing damage to underground pipelines due to excavation. Finally, the Commission recognizes that TxDOT is charged with protecting the safety of the traveling public, and that there may be instances in which exempting TxDOT's operations from the scope of the new rules will greatly enhance the ability of TxDOT to perform its vital mission and, at the same time, will not be likely to cause harm to the safety and welfare of the public. These exemptions are discussed in greater detail in subsequent paragraphs.

PHMSA applauded the Commission for its timely and comprehensive implementation of the requirements imposed by the Texas Legislature in recent amendments to §117.012 of the Texas Natural Resources Code and §121.201 of the Texas Utilities Code. PHMSA acknowledged that Mary McDaniel and her staff have worked very hard to secure input from affected stakeholders in developing this proposal, and the end product reflects that hard work. PHMSA noted that the proposed rules appear to be consistent with the Pipeline Safety Improvement Act of 2002, Public Law 107-355, and the Pipeline Inspection, Protection, Enforcement, and Safety Act of 2006, Public Law 109-468, (PIPES Act), 49 U.S.C. §6105 et seq., and the Common Ground Alliance (CGA) Best Practices. PHMSA acknowledged that there may be some revision due to comments received during the public comment period but anticipated adoption of the new rules substantially as proposed. The Commission appreciates PHMSA's comments and notes that the changes made in the adopted versions of the new rules are for clarification, and do not diminish the effectiveness of the rules as proposed.

Texas Gas reviewed the proposed new rules and limited its separate comments to proposed new §18.12 and Table 1, but stated its support and adoption of the comments filed by Atmos and CenterPoint.

TPA commented that securing tougher damage prevention laws and enforcement of those provisions is a top priority of the pipeline industry. TPA extended great thanks to the Commission and its staff for the time spent ensuring a deliberate open process in which the proposed rules were developed. Overall, the rules are a great first step toward improving pipeline safety and meeting the requirements of the recent and past pipeline safety acts and the spirit of the CGA Best Practices.

TPA offered several comments regarding specific provisions of the proposed rules. TPA supports the extensive comments developed by the Coalition, which developed a number of recommendations and suggestions that will clarify several provisions of the proposed rules in addition addressing concerns relating to the penalty rule. TPA commented that the proposed rules are a great first step in moving Texas forward to creating and enforcing damage prevention standards that will assist in keeping our state's energy infrastructure and the general public safer, and noted that damage prevention efforts will be successful only to the degree that all stakeholders take an active role to ensure their actions are responsible. TPA believed the rules are aligned with the concepts of the Common Ground Alliance and were written with the input from any stakeholders wishing to be included in the process. The Commission thanks TPA for its participation in the rulemaking process and for its support of efforts to improve the standards for pipeline damage prevention.

TGA is an association comprising approximately 90 distribution and transmission companies in Texas, including municipal gas distribution systems and investor-owned distribution and transmission companies throughout the State of Texas. These systems account for over ninety-nine percent of the natural gas customer base in the state. TGA noted that its comments may not represent the opinion of each and every member, and that some members are being represented by other organizations and others will be submitting individual comments. TGA supports the efforts of the legislature and the Railroad Commission to protect underground pipelines and to reduce third-party damage to these pipelines which would increase the safety of the workers around pipelines as well as the general public. TGA commended the Pipeline Safety Division for developing the new rules under the guidance of Mary McDaniel, P.E., Director of Pipeline Safety. TGA acknowledged in particular Ms. McDaniel, the Commission staff, and others who devoted time and effort to the development of the rules for the even-handed development of difficult rules, and urged the support of the industry for the new rules. The development of rules like these requires fairness and balance, which was shown in the proposal. TGA offered comments in an effort to help develop rules that are equitable to all parties and to enhance the efforts of the Pipeline Safety Division. The Commission thanks TGA for its participation in the rulemaking process and for its comments and suggestions on the new rules.

OXY stated its appreciation for the opportunity to participate in developing, reviewing, and commenting on the proposed new rules. OXY supports the Commission's efforts to protect underground pipelines, improve public safety, and allow for operators and excavators to agree to special protocols on large projects. These options should encourage cooperation, reduce third-party damage, and better protect workers and the public. OXY offered specific comments in an effort to further develop and clarify the

rules to enhance these efforts. The Commission thanks OXY for its participation in the rulemaking process and for its comments and suggestions on the new rules.

The Coalition consists of 12 major pipeline operators in the state including Anadarko, Atmos, Chevron, Copano, Dow, DCP Midstream (formerly Duke Energy Field Services), Energy Transfer, Enterprise, ExxonMobil, Magellan Midstream, Shell, and Williams. The Coalition is dedicated to developing stronger damage prevention laws that further protect pipeline facilities in Texas. The Coalition appreciated the opportunity to comment on the proposed rules that implement the provisions of House Bill 2161 and Senate Bill 9 passed by the 79th Legislature.

The Coalition extended great thanks to all of the Commission staff and Commissioners' offices for the efforts relating to the new rules. The Coalition commented that the Commission staff did a remarkable job of evaluating the issues from all stakeholder groups when developing and drafting the proposed rules. Open dialog between affected stakeholder groups occurred throughout the process, especially during three public stakeholder workshops held over the course of a nine-month period. Feedback was requested and given throughout the process in order to address the needs, concerns and best interests of pipeline operators, damage prevention stakeholders, and the public at large.

The Coalition noted that the pipeline industry has a unique position within the group of underground facilities. While each day the pipeline industry strives to keep pipeline systems operating safely and efficiently, the greatest risk to daily operations is that of external force. Adopting the damage prevention rules will be a major accomplishment and step in the right direction with regard to underground damage prevention, specifically underground damage prevention in the State of Texas.

The Coalition reiterated its support for the rules, and thanked the staff and Commissioners for their time and effort in making the rules a reality. The Coalition looks forward to working with staff and the Commissioners to address the issues outlined in these comments.

The Coalition offered support on several specific provisions of the rules that will assist with advancing damage prevention efforts in Texas. First, the rules address long-standing unconformity with regard to the applicability of damage prevention requirements for all stakeholders. Damage prevention standards should be followed by, and applied to, all stakeholders regardless of ownership, activity, or status. The draft rules establish a clear and consistent depth requirement for all excavation. Further, the rules permit a review of exemptions by the Commission if unique circumstances arise.

Second, the rules are based on the Common Ground Alliance Best Practices. The Common Ground Alliance is a non-profit organization dedicated to improving damage prevention efforts by all affected stakeholders. The Common Ground Alliance Best Practices are developed by consensus with the feedback and approval of all underground damage stakeholders including the pipeline industry, contractors and excavators, telecommunication and electric industries, state one call notification systems, locator groups, government representatives, emergency responders, insurance groups, public-works departments, and railroads. Representatives from all of these industries and backgrounds are in agreement that these standards are the minimum best standards that should be implemented to improve damage prevention efforts throughout the nation.

The Coalition noted that the pipeline industry is striving to improve a number of areas that directly relate to the security and integrity of pipeline infrastructure. Damage prevention is one of these areas. In Texas, damage to underground facilities by third parties remains the leading cause for pipeline accidents. In fact, the rate of damage by third parties in Texas far exceeds the national average. The pipeline industry is a strong supporter of tougher damage prevention laws and enforcement of those provisions, and believes that efforts like this rulemaking are a positive step toward addressing third-party damage.

Third, the Coalition stated that the rules will address the requirements of the Pipeline Safety Act (PSA) of 2002 and the Pipeline Inspection, Protection, Enforcement, and Safety (PIPES) Act of 2006, which will provide additional resources to the Commission for implementing and enforcing these provisions. The Coalition believes the rules meet the intent of the PSA 2002 and will be able to satisfy the requirements of the PIPES Act of 2006. The rulemaking process was an open process that encouraged the involvement of all stakeholder groups. And, once implemented, the enforcement process will engage all stakeholders in the review and enforcement of the Railroad Commission rules. The Coalition looks forward to working with the Commission to develop this process in a manner that provides the greatest improvement to damage prevention knowledge, compliance, and enforcement that can be achieved.

Atmos commented that the wording of proposed §18.1(c), which states that persons exempt under Texas Utilities Code, Chapter 251 "may" be required to comply with new Chapter 18 requirements, creates ambiguity concerning the scope of Chapter 18. Atmos suggested that this language be revised to read as follows: "(c) Persons that are exempt from the provisions of Texas Utilities Code, Chapter 251, are required to comply with this Chapter unless the person is exempted under the provisions of subsection (d) of this Section."

Atmos pointed out that, generally stated, the proposed rule would apply to all persons engaged in the movement of earth in the vicinity of an intrastate pipeline. Every day gas distribution operators respond to gas leak reports. A proper investigation of a gas leak report involves probing the earth in order to take gas concentration readings which allow the investigator to determine the source of the odor. While it is unclear under the proposed rule whether a gas operator would have to physically mark its own lines prior to investigating a potential gas leak and whether it would have to report inadvertent damage to its own facilities, the fact remains that under the proposed rule, prior to placing the initial probe bar in the ground to investigate a potential gas leak, an emergency locate request would have to be placed to a one call center with the corresponding two-hour waiting period because another intrastate gas, hazardous liquid, or carbon dioxide operator may have facilities in the area. Atmos submits that the safety issues inherent to a leak investigation outweigh the potential third-party damage issues to other pipeline facilities and requests that the specific act of leak investigation be exempted from the rule by adding an additional exemption for gas leak investigations as paragraph (4) in §18.1(d).

The Commission agrees that the wording of §18.1(c) lacks necessary specificity, and has incorporated Atmos's suggested change into the adopted rule. The Commission disagrees with Atmos's second comment that a leak investigation on a pipeline's own facilities be exempt, but notes the following. In the process of the workshop discussions, the term "probing" was removed from the definition of "movement of earth" at the

request of the distribution utilities specifically to accommodate the need to perform leak investigations. However, "digging" and "excavating" are still within the scope of the definition of "movement of earth," and would require an emergency locate request.

TxDOT recommended that the possible exemptions that may apply as listed in proposed §18.1(c) be further outlined because the term "*may* be required" is too ambiguous and leaves open the question of what criteria the requirement is based on. The Coalition also commented that proposed §18.1(c) is ambiguous. As stated in response to other comments, the Commission has modified the provision.

Devon noted that §18.1(d) retains exemptions in Texas Utilities Code, §251.003, and specifically, paragraph (5), which states "the portion of an exploration and production underground facility that is located within the boundaries of the oil or gas field from which the oil and gas is produced and that is not located in the boundaries of an established easement or right-of-way granted for the benefit of a governmental entity or a private entity if the easement or right-of-way is granted for a public purpose." Devon advised the Commission that even though operators may choose to cover all or a portion of its exempt pipelines with One Call service, these lines are still exempt and not subject to Chapter 18. Devon argued that exempt status will not always be simple to determine and questioned whether the operator can assume that an easement or right-of-way for an above ground utility has no bearing on the exemption. Operators will know if their pipeline crosses the boundaries of an established easement or right-of-way but they will not necessarily know if the easement or right-of-way is granted for a public purpose.

Devon noted that the Texas Pipeline Mapping System could be used to identify any pipelines with utility status and thus have a right-of-way for a public purpose. However, non-pipeline utilities are not mapped by TPMS. This seems to leave only one alternative: the operator would have to do a field survey to confirm that the excavation did not occur within the boundaries of a covered easement or right-of-way. The operator could then make a good faith declaration that the pipeline in question was indeed exempt under Utilities Code, §251.003(5). Devon argued that sufficient time should be allowed for the operator to resolve any issues concerning exempt status before the issue is sent for an administrative hearing.

Devon also stated that it is important to have comprehensive data on damage to pipelines in order to develop the best possible damage prevention program for Texas. Under the present regulations the Commission should encourage operators to report damage to all pipelines whether or not they are covered by Texas One Call legislation. But voluntary reporting does not affect the exemption that certain pipelines have from Chapter 18 requirements.

The Commission recognizes that it may be difficult to determine how or whether the exemption in Utilities Code, §251.003(5) applies in any particular situation, but disagrees that using TPMS and easement records is sufficient for safe excavation operations in the vicinity of underground pipelines. The Commission notes that even if the TPMS is accurate to within 500 feet, that's still insufficient for safe excavation. Moreover, distribution systems are not included in TPMS. The Commission concedes that these new rules are not perfect, but they are a good beginning and a significant improvement over the current state of excavation standards. The Commission fully expects to amend these rules from time to time as the industries and the regulators gain experience and the technical resources improve.

With respect to §18.1(d)(1), which incorporates into Chapter 18 the exemptions in Texas Utilities Code, §251.003, TxDOT estimated that this provision will result in an additional 382,000 calls being made annually to One Call by TxDOT maintenance operation personnel. TxDOT noted that the Texas Legislature exempted TxDOT from Texas Utilities Code, §251.004, but new §18.1(d) refers to only to Texas Utilities Code, 251.003. TxDOT urged that contractors working in the TxDOT right-of-way and TxDOT employees excavating in or near department right-of-way should be exempt from the requirements contained in the proposed rules, and recommended that §18.1(d)(1) be revised to refer to both Texas Utilities Code, §251.003 and §251.004.

The Commission agrees in part and disagrees in part with this comment. The experience of the notification centers and the Commission is that TxDOT employees and contractors have been making locate calls, so the Commission did not anticipate that there would be 382,000 additional calls. Nevertheless, the Commission recognizes that because TxDOT has its own important mandate to protect the safety of the traveling public, there are certain maintenance activities performed by TxDOT employees that it is reasonable to exempt from the provisions of Chapter 18. The Commission finds that exempting from the scope of Chapter 18 the following activities when performed by TxDOT employees in TxDOT right-of-way is in the public interest and is not likely to cause harm to the safety and welfare of the public: sampling and repair of pavement, base, and subgrade; repair of roadway embankment adjacent to pavement structure; reshaping of unpaved shoulders and drop-offs; installation and maintenance of guardrails, cable barriers, delineators, vehicle attenuators, sign posts, mailboxes;, and cables for traffic signals and luminaries; cleaning of ditches; and removal of silt from culverts. Further, the Commission finds that exempting hand digging by an employee or contractor of TxDOT for TxDOT's archeological program is in the public interest and is not likely to cause harm to the safety and welfare of the public. The Commission adopts §18.1(d) with these additional exemptions.

With respect to §18.1(e), OXY supports the clarification that any movement of earth deeper than 16 inches requires making a locate call, marking the proposed excavation, and ensuring that there is a positive response. OXY anticipates that significant education efforts will be needed by both industry and the Commission to apprise agricultural interests of the possible impact to their operations. The Commission commends OXY for its commitment to public education efforts, and notes that API-1162 contains new requirements for public education and new performance measures and that the new 811-Call Before You Dig Program starts in May, 2007.

With respect to §18.1(e), Marathon commented that the chapter should apply to movement of earth by tillage that exceeds a depth of 12 inches rather than 16 inches. This is consistent with other states' current requirements. There is little agricultural tillage between 12 inches and 16 inches, so there should be little affect of changing to the more consistent dimension. The Commission notes that two of the statutes under which the rules were proposed and are being adopted, Texas Natural Resources Code, §117.012, and Texas Utilities Code, §121.201, limit the scope of the Commission's authority to adopt safety standards related to the prevention of damage to underground pipelines to the movement of earth by a person in the vicinity of the facility, other than movement by tillage to a depth of 16 inches or less.

The Commission is focusing the effort of this rulemaking toward establishing the consistent application of the national Best Practices in Texas; the national standards are still set at 16 inches or greater.

The Smalley Foundation also approves of the mandate requiring notice of TxDOT excavation exceeding a depth of 16 inches, rather than 24 inches. The Smalley Foundation has conducted pipeline safety education classes for TxDOT workers and have found them to be receptive and in need of such training. This more restrictive rule will help to insure their safety and the safety of others. The Smalley Foundation also suggested that the state offer pipeline safety and public awareness classes to its TxDOT workers in the future. More education equals better safety. The Commission agrees that more education is helpful.

New §18.1(f) provides that, unless otherwise specified, all time periods used in this chapter shall be calculated from the time the original notification is given to the notification center. New subsection (g) provides that unless otherwise specified, all time periods are stated in working days. Subsection (h) states that unless an excavator and an operator otherwise expressly agree, the life of a line locate ticket shall be 14 days. Marathon commented that it is ambiguous and unclear as to the meaning of the 14 days language. To Marathon, "14 days" implied two weeks. Marathon suggested that this be changed to 15 days if the intent is 3 weeks or change to 14 calendar days.

The Commission agrees that the wording, as proposed, was not clear. In the rule workshops, the clear preference was for all time periods to be working days, which is a defined term in §18.2(25). The Commission also intended that the general provision in §18.1(g) be understood as meaning that any time period that is stated in days would mean working days. However, from this and other comments, the Commission recognizes that the general provision should be revised to say exactly that. As adopted, new §18.1(g) states that unless otherwise specified, all time periods that are stated in days shall mean working days.

Air Products commented on §18.1(h) that the wording should be amended to say "working" days. The Commission disagrees with this comment; as adopted, §18(g) states that unless otherwise specified, all time periods that are stated in days shall mean working days, which is a defined term in §18.2(25).

SM&P commented on the provision that the life of a locate ticket will be set at 14 working days. This proposed time frame and language would allow excavators to dig when locate marks have been altered or destroyed either by work activity or weather. There is much potential for error when weather or other factors make previously and correctly marked lines difficult to read or faded. It is not in the best interest of public safety to allow excavators to dig while these conditions exist. SM&P would propose additional language be added to the statute indicting that the life of a locate ticket shall be the shorter of 14 days or when the locate marks become altered or destroyed.

The Commission disagrees with this comment. The rules distinguish between the life of a locate ticket, which is 14 working days unless otherwise agreed, and the viability of locate markings, which is variable. The provision regarding the life of a locate ticket must be read in conjunction with new §18.4(g), which provides that an excavator must protect and preserve locate markings from the time the excavator begins work until markings are no longer required for the proper and safe excavation in the vicinity of all underground pipelines. Clearly, the rules require that markings be visible at the time of excavation.

TGA commented that in addition to specifying the life of a locate ticket, the rules should address the size (scope) of a locate ticket. The size of the locate ticket should be what could reasonably be expected to be excavated in the 14 days of the life of the ticket. Currently, a locate ticket *can* be several miles, much longer than could possibly be excavated in the 14 day life of the locate ticket, resulting in markings being made that will not possibly be used, markings being lost or damaged, and, additionally, causing a refresh or update of the original locate ticket to be required.

The Commission agrees that specifying the size and scope of a locate ticket is a Best Practice, and it is an issue that may be addressed in future rulemakings. For the present, however, it is possible for an excavator and an operator to negotiate and agree on the protocols applicable to an excavation site in the vicinity of underground pipelines based on the particular characteristics of each job. Pursuant to new §18.9(a)(9) (proposed as §18.9(a)(8)), the size and scope of locate tickets for a specific project could be considered "any other agreement with respect to excavation activities and/or marking requirements that will or will tend to ensure the proper and safe excavation in the vicinity of an underground pipeline." As the Commission and the industry gain experience with these rules, and more specifically with agreements under new §18.9, it will be appropriate to re-visit the issues attendant to the size and scope of locate tickets.

Air Products commented that §18.1(i) should be amended to include the following statement: "Records shall include one call tickets and positive response notifications. Retention of one call tickets at the One call Center is an acceptable method for retention."

The Commission agrees that providing examples of the kinds of records that need to be retained is useful; however, the Commission notes that there may be records in addition to those listed that excavators and operators might need to retain. Therefore the Commission has added a slightly different clarification than the one suggested by Air Products in the adopted rule: "At a minimum, each operator and each excavator shall retain locate tickets and positive response notifications. Retention at a notification center is an acceptable method of retention for locate tickets."

With respect to new §18.2(1), Devon Energy commented that defining "defacing" as pipeline damage is problematic. New §18.2(1)(A) and Texas Utilities Code, §251.002(4)(A) both define damage as including but not limited to "defacing, scraping, displacement, penetration, destruction, or partial or complete severance of an underground pipeline or of any protective coating, housing, or other protective device of an underground pipeline." The Merriam-Webster Online dictionary defines "defacing" as "to mar the appearance of: injure by effacing significant details." Of the named damages, Devon asserted that "defacing" is the least injurious to pipe integrity, and therefore should be removed from the Chapter 18 definitions because, by definition, it mars only the protective coating and does not necessarily compromise its function.

The Commission disagrees with Devon's suggestion to remove "defacing" as an element of the definition of "damage." While "defacing" may be the least injurious, it can still result in corrosion and, ultimately, failure. Adopting this definition makes the rules in Chapter 18 consistent with the standards in Texas Utilities Code, Chapter 251, that have been in place since 1999.

There were several comments on the definition of "emergency" in §18.2(3). CenterPoint observed that Texas Utilities Code,

§251.155, currently exempts emergency excavations from the 48-hour notice requirement otherwise required by the law. The law, however, requires the excavator responding to an emergency situation to notify the notification center "as promptly as reasonably possible." In recognition of the need to rapidly respond to public emergencies, CenterPoint has traditionally given such calls priority in its locating system and tries to respond to them within four hours of receipt of the call. Unfortunately, CenterPoint noted, some excavators attempt to avoid the 48-hour notice requirement by calling in location requests as emergencies when, in fact, the situations do not qualify under the exemption. This abuse of the system overloads the locating resources of an operator and makes it more difficult to respond to locate requests by excavators who are complying with the intent of the statute. CenterPoint commented that the Commission correctly recognizes the seriousness of this problem by creating a penalty for a false report of an emergency line locate request in item no. 2 of the penalty calculation worksheet, but noted that there is no corresponding text in proposed Chapter 18 prohibiting excavators from calling in a false emergency. As part of CenterPoint's recommendation on implementing the prohibition contemplated by the penalty schedule, and to harmonize this with the Texas One Call Law, CenterPoint also suggested that the definition of an emergency in §18.2(3) be changed to match the corresponding definition in Texas Utilities Code, §251.155(a), by substituting the following definition of "emergency" for the one that was proposed: "a situation that endangers life, health, or property or a situation in which the public need for uninterrupted service and immediate re-establishment of service if services are interrupted compels immediate action."

The Commission agrees in part and disagrees in part with CenterPoint's comments. The Commission agrees that the definition of "emergency" in §18.2(3) should be changed to match the definition in Texas Utilities Code, §251.155(a), and has made the suggested change in the adopted rules. However, the Commission has reconsidered its proposal to penalize the false reporting of an emergency locate request. The Commission has determined that, ultimately, it is within the purview of the Texas One Call Board to determine and enforce standards for emergency locate requests. The false emergency locate requests are clearly a resource issue for operators, but not of the same magnitude, in terms of safety, as failure to locate, failure to make a positive response, or failure to give notice of intent to excavate. The Commission has removed the penalty proposed in Table 1, line 2.

With respect to the definition of "emergency," TxDOT commented that the ability to excavate in an emergency without making the call to the notification center is not clearly stated in the rules. One important need for the Texas Utilities Code, §251.004, exemption arises when TxDOT's archeology staff responds to emergency archeological discoveries. The Archeology Branch and its contractors normally do utilize the Texas One Call system prior to backhoe trenching and other forms of mechanical ground disturbance in the existing and proposed right-of-way, but the exemption is essential to allow for timely response to emergency discoveries of cultural resources discovered during construction, which do not meet the definition of "emergency" under the proposed rule. The Commission finds that by amending the definition of "emergency" in the adopted rules, as explained with respect to CenterPoint's comment, and by adopting specific exemptions for certain TxDOT activities, TxDOT will be able to respond to emergency archeological discoveries. Further, the adopted definition of "emergency" includes a situation that endangers "property," which the Commission would recognize as including cultural resources discovered during excavation or construction.

With respect to the definition of "excavate" in §18.2(4), Air Products commented that there should be an exception for locating a pipeline in response to a notification from the Texas One Call System. The Commission declines to make this change, however, because in the process of the workshop discussions, the term "probing" was removed from the definition of "movement of earth" at the request of the distribution utilities specifically to accommodate the need to perform leak investigations. However, "digging" and "excavating" are still within the scope of the definition of "movement of earth," and would require an emergency locate request.

TxDOT commented on the definition of "hand digging" in §18.2(6). Specifically, TxDOT noted that the existing rule (Texas Utilities Code, Chapter 251) applies to mechanical forms of excavation only. This is the most critical difference between the two rules (Texas Utilities Code, Chapter 251, and the Commission's rules in Chapter 18) with regard to its impact on TxDOT archeological activities. To satisfy its responsibilities under federal and state antiquity laws, TxDOT's archeology program and its contractors excavate literally thousands of holes (shovel tests and excavation units) by hand every year in existing and proposed right-of-way. TxDOT is unaware of any case where such activity has resulted in damage to a facility that is the subject of the proposed rules. Moreover, because archeology is inherently a process of discovery, work localities within a project area are often unpredictable and evolutionary, necessitating further delays as revisits are conducted to clear other loci within a given project area. If this provision is adopted, and hand excavated holes must be coordinated for utility location according to the procedures outlined, time demands and costs to TxDOT will skyrocket, and the agency's ability to meet the demands of construction letting schedules will suffer, delaying needed highway construction projects. The Commission has adopted §18.1(d) with an exemption for hand digging by an employee or contractor of TxDOT for TxDOT's archeological program.

Equistar and OXY commented on the definition of "legal holiday" in §18.2(7) as a holiday specified as a legal holiday by Subchapter B, Chapter 662, Texas Government Code. Equistar stated that since the industry does not recognize Texas state holidays, specific reference to Texas state holidays will cause operators and/or excavators to inadvertently violate the time periods mandated for giving excavation notices and making positive responses. Equistar recommend that there be no distinction with respect to state holidays in the new rules. OXY stated its concern with the inclusion of the Texas state legal holidays. Most businesses recognize the federal holidays but do not recognize the eight state holidays. This could lead to some notice or positive response issues, particularly related to state agencies such as the Department of Transportation.

The Commission disagrees with these comments and declines to make a change to this definition. The list of legal holidays is objective and is available to everyone. Whether an excavator or an operator is working on any particular day is irrelevant to the manner in which the time lines are calculated. Further, an excavator and an operator may agree to some other manner of calculating deadlines, pursuant to new §18.9, Options for Managing an Excavation Site in the Vicinity of an Underground Pipeline.

Air Products commented that the definition of "locator" in §18.2 should include the location of the vertical location of an under-

ground pipeline. The Commission disagrees with this suggestion. This issue was raised and discussed at some length in the workshops. The Commission agrees that this issue may need to be addressed in future reviews of what constitutes the best practices in locating pipelines, but must recognize the reality that vertical location technology is not developed to the necessary degree of accuracy.

TxDOT commented that the definition of "movement of earth" in §18.2(11) is overly restrictive. The term "moved" would mean TxDOT's maintenance crews could not so much as straighten a leaning delineator sign post without making a call to a notification center. The definition would even require making a call to a notification center, with the attendant delays, when performing critical functions such as repairing guardrail posts or sign posts, or clearing ditches of sedimentation. These are activities that, in order to protect the safety of the traveling public, must be performed without delay. None of these types of activities pose a real threat to pipelines. In addition, the restriction on movement over a depth of 16 inches would severely hamper the environmental and archeological duties and activities of TxDOT's Environmental Affairs Division who must routinely dig below a depth of 16 inches. The Commission has agreed in part with these comments and has adopted an exemption from the rules for certain activities when performed by TxDOT employees in TxDOT right-of-way.

CenterPoint suggested that the definition of "notification center" in §18.2(13) be slightly amended to insert the words "Subchapter C" at the end. This change clarifies that the definition refers only to notification centers receiving and disseminating notices of excavation, and not the Texas Underground Facilities Notification Corporation d/b/a Texas One Call Board, which is another legal entity that is established pursuant to Chapter 251 of the Texas Utilities Code. The Commission agrees with this suggestion and has made this clarifying change in the adopted rule.

The proposed definition of "positive response" in §18.2(17) received several comments. Marathon proposed that the positive response system be defined to be administrated through the one call center rather than responding directly to the excavator. This type of system will be much more effective communication whether a response has occurred and thus much more effective in preventing damage and personal injury. The Commission recognizes that it would be efficient to administer the positive response requirement through the notification centers; however, because the Commission does not have jurisdiction or authority over the notification centers, the Commission cannot require them to take any particular action. The Commission is unable to make the suggested change.

CenterPoint suggested that the phrase "to an excavator" be inserted after the word "notification." This would be a clarification that the notification contemplated by the positive response definition relates to required notifications to excavators. The Commission agrees and has made this clarifying change.

TPA strongly urged the Commission to clarify the manner in which operators will be required to provide a positive response under §18.2(17). As the rule is currently drafted, there are no limitations as to the number of ways a pipeline operator may be required to provide a positive response to an excavator. TPA requested that the manner in which a positive response is given be limited to several options, specifically by fax, phone, e-mail or written correspondence. TPA believes this is an adequate list of options that will accommodate the needs of both pipelines and excavators. The Commission agrees with this comment and has made the suggested clarifying change, along with the addition of "pager" as a method for providing a positive response.

The Coalition addressed the use of the term "planned excavation" in this definition and in new §18.3(a) and (d). Pipeline operators are concerned with all excavation activities that have the potential to damage or disrupt pipeline operations regardless of whether or not they are planned. The Coalition asserted that through the use of the word "planned," the proposed rules imply that certain types of excavation activities are covered by this rule while others are not. The Coalition expressed concern that if the word "planned" remains in the rule, those entities required to follow rule could use "planned" as a means of circumventing the requirements and intent of the rule. For this reason, the Coalition sought to have the word "planned" struck throughout the preamble and proposed rule. The Coalition also suggested that the manner of a positive response be limited to fax, telephone, e-mail, written correspondence, or other methods approved by the Commission, and that "other shared or transmitted information" not be permitted as a form of positive response.

The Commission agrees in part with this comment. The Coalition makes a good point with respect to the use of the term "planned," although there are no "accidental" excavations and the only difference is whether the planning is done well in advance or under emergency conditions. Nevertheless, the word is not critical to the proper functioning of the new rules in Chapter 18, and the Commission has removed it from §18.2(17) and §18.3(a) and (d) in the adopted rules. The Commission agrees with the Coalition's suggestion that the manner of positive response be limited, and with removing "other shared or transmitted information" as a permissible manner of providing a positive response. The Commission has included "pager" as an acceptable means of providing a positive response, but has not included "or other methods approved by the Commission" to make it clear that only the methods listed in the definition may be used to provide a positive response.

With respect to the definition of "tolerance zone," Air Products suggested adding an alternative definition of "tolerance zones defined by operator easement privileges." The Commission disagrees with this suggestion; easements are simply not precise enough to ensure accurate pipeline location.

AGC of Texas commented that the definition of "tolerance zone" should be clarified to reflect that the tolerance zone applies to the marks used to locate the facility. The Commission disagrees with this comment. A tolerance zone is measured from the center of the pipe, not from the markings, which is only an approximate center line.

Marathon requested further clarification, and offered this alternative definition of "tolerance zone": "the area between the vertical planes18 inches on either side of the outside edge of the underground pipeline on a horizontal plane." The Commission disagrees with the use of vertical locations at this time because the technology is still emerging, its use is not widespread, and the results are still too variable to be reliable.

TxOGA commented that it respects the definition of "tolerance zone" in the proposed rule, but would like to see the tolerance zone larger in order to provide for greater safety standards for excavation near an underground pipeline facility, particularly for larger transmission systems. TxOGA wanted to reserve the right to request the tolerance zone be increased at a later time.

The Commission disagrees with this comment; the size of and the method for measuring a tolerance zone were issues that

were thoroughly discussed in the workshops and resolved by consensus. At this time, the Commission prefers to move forward with adopting the national Best Practices. However, the Commission will be reviewing the information reported through the automated system and will certainly revisit this issue if it appears necessary. Finally, the Commission agrees that any interested person can petition the Commission to initiate a rulemaking.

OXY suggested an additional alternative for defining a tolerance zone: "as reasonably designated by the pipeline operator to allow for protection of large size pipes or as agreed to in a writing between the excavator and the operator." The Commission declines to add this to the definition of "tolerance zone," because it is not necessary. Under new §18.9(a)(8) (proposed as §18.9(a)(7)), an excavator and an operator would be able to designate the extent of the tolerance zone (provided that it is not less than half the nominal diameter of the underground pipeline plus a minimum of 18 inches on either side of the outside edge of the underground pipeline on a horizontal plane) and the type of excavation permitted within the tolerance zone as part of an optional agreement for managing an excavation site in the vicinity of an underground pipeline.

The Commission adopts a corrected definition of "tolerance zone" in new §18.2(21); instead of the word "width" in the proposed definition, the adopted rule substitutes the term "nominal diameter."

Devon commented on the definition of "TDRF" in new §18.2(22) that information on the Texas Damage Reporting Form should be readily available to operators and excavators so that everyone involved in a particular incident will have to the opportunity to view information reported. Additionally, it would be helpful if those involved in a particular incident could use this system to dispute any information they consider incorrect or incomplete.

The Commission notes that the information submitted using TDRF will be available on line for everyone to view before the September 1, 2007, effective date of the new rules in Chapter 18. An operator and an excavator can (and should) both file reports on the same incident, and both will be accepted. In addition, a member of the public or a government employee could also file reports through the TDRF system.

TxDOT suggested revising the definition for "underground pipeline" provided in §18.2(23) to include a definition of "intrastate pipeline." The Commission disagrees with this suggestion. The intrastate or interstate nature of a pipeline is irrelevant to whether a locate call needs to be made. The only significance of whether a pipeline is intrastate or interstate is whether the Railroad Commission has jurisdiction over its operator for purposes of the new rules in Chapter 18.

The provision in new §18.3, relating to excavator notice to notification center, garnered many comments. Atmos commented that the proposed rule inappropriately confers upon the excavator the latitude to determine the methodology for providing positive response. Simply stated, an intrastate pipeline operator cannot be expected to comply with varied positive response methodologies based upon the convenience or whim of the excavator. The rule needs to establish a standardized positive response protocol that an intrastate pipeline operator can build into its process and use consistently for each and every line locate. Atmos suggests that the standardized positive response approach should include either marking the facility, including an "all clear" designation if appropriate, or an electronic acknowledgment sent by the operator to the one call center that the excavator can access. As noted below, the time for positive response should not reduce the statutory time frame for actual marking of lines.

Proposed §18.3 also provides that if an excavation project is too large or too expansive for description on a line locate ticket, the operator and excavator must have a face-to-face meeting. It is unclear from the proposed rule whether the excavator can determine on his own that the project is too large or too expansive, whether an operator who receives a large marking request can determine that it is too large or too expansive, or whether the excavator and all potentially impacted intrastate pipeline operators must agree to a face-to-face meeting. The Commission should revise this portion of the proposed rule in order to clarify how the face-to-face meeting provision will work.

The Commission agrees in part with Atmos's first comment regarding limiting the manner in which a positive response is to be given to an excavator. This was a subject of lengthy discussions in the workshops, which showed that this issue demands both specificity and flexibility. The Commission makes no change in §18.3 and instead adopts new §18.2(17) with clarifying changes that allow a positive response to be given by markings left at an excavation site, fax, phone, e-mail, pager, or written correspondence.

The Commission disagrees with Atmos's second comment regarding the requirement to conduct a face-to-face meeting. The initial determination of whether an excavation project is "too large" to be described on a locate ticket would be made by an excavator. However, an operator always has an option to request such a meeting, as well as an option to use the provisions of new §18.9 to work with the excavator to jointly establish the protocols applicable to an excavation site in the vicinity of underground pipelines, based on the particular characteristics of each job. As the rule states, such protocols may designate the contact person or persons for each entity working at an excavation site; establish the required mode or modes of communication among all entities working at an excavation site, e.g., telephone or other electronic means or face-to-face meetings at prescribed times or intervals; provide the method for coordinating work activities among all entities working at an excavation site; provide for the ownership and/or possession of the locate ticket or tickets; declare which entity or entities must have the locate ticket or locate ticket number before beginning work; state the life of a locate ticket and the circumstances that require refreshing the locate ticket; designate the extent of the tolerance zone (provided that it is not less than 24 inches) and the type of excavation permitted within the tolerance zone; and provide for any other agreement with respect to excavation activities and/or marking requirements that will or will tend to ensure the proper and safe excavation in the vicinity of an underground pipeline.

SM&P commented that proposed new §18.3 does not provide enough detail and definition as to what are acceptable methods of positive response. This lack of definition allows too much discretion for an individual to designate method of positive response that is overly difficult to execute or inadequate. An example would be an excavator designating a site visit as the chosen method of positive response when the operator, due to geographic limitations, cannot provide coverage on site within the expiration time of the ticket. Further, as written, the rules do not delineate what responsibility the excavator will have to monitor its chosen method of positive response. The methodology of positive response should not be unilaterally decided upon by ei-

ther party. SM&P would suggest that a standardized method of positive response be developed for all parties to follow. In addition, in today's world of electronic communications, it can often be the case that communication becomes difficult due to many factors including geographic wireless coverage gaps, over-taxed communication networks, and messaging limitations due individuals' personal communication habits. SM&P stated that an excavator should have a positive duty to fully monitor and receive response communications from an operator.

The Commission reiterates the response given with respect to Atmos's comments on new §18.3. The Commission adopts new §18.2(17) with clarifying changes that allow a positive response to be given by markings left at an excavation site, fax, phone, e-mail, pager, or written correspondence. The new rules impose an affirmative duty on both excavators and operators to communicate clearly and directly with each other.

CenterPoint commented that even though both the Texas One Call Law (Texas Utilities Code, Chapter 251) and the Commission's proposed rules require an excavator to identify the location of a proposed excavation by providing certain specific information, neither regulatory scheme currently imposes a limit on the size of the area that can be included in one ticket. In many cases, tickets are called in for areas that are so large that the ticket cannot be practically located within the 48 hour time limit. In other cases, the location information is not specific enough, though white-lining can clarify any ambiguity.

CenterPoint understands that the Texas One Call Board is considering a change to the technical standards for notification centers that would limit the size of the area that could be included on one ticket. This change could alleviate some of these hardships. The Commission's proposed rules recognize the need for even more definition in cases of large excavations by requiring that excavators and operators enter into protocols to further define the marking process for such projects (see §18.3 and §18.10). Those two rules should require that the protocols include a schedule of the contractor's work so that the operator may phase its marking work to match the progress of the excavation.

The Commission recognizes that the scope and size of a locate request is an issue that may be the subject of a future rulemaking, but must recognize that the Commission will have limited, if any, authority with respect to the way in which notification centers structure locate tickets. The workshop discussions did not yield a clear consensus on how to manage these issues. However, the rules provide a couple of methods for handling large projects. One is the face-to-face meeting requirement in §18.3(d); the other is the option provided in new §18.9 that would allow an excavator and an operator to jointly establish protocols for managing excavations sites, regardless of the size of the project.

CenterPoint also commented that the Texas One Call Law presently exempts emergency excavations from the 48-hour notice requirement otherwise required by the law (Texas Utilities Code, §251.155). The law, however, requires that the excavator responding to an emergency situation notify the notification center "as promptly as reasonably possible." In recognition of the need to rapidly respond to public emergencies, CenterPoint has traditionally given such calls priority in its locating system and tries to respond to them within four hours of receipt of the call. Unfortunately, some excavators attempt to avoid the 48-hour notice requirement by calling in excavations as emergencies that in fact do not qualify under the exemption. This abuse of the system overloads the locating resources of an operator and makes it more difficult to respond to locate requests by excavators who are complying with the intent of the statute. The Commission correctly recognizes the seriousness of this problem by creating a penalty for a false report of an emergency line locate request in item no. 2 of the penalty calculation worksheet. However, there is no corresponding text in proposed Chapter 18 prohibiting excavators from calling in a false emergency. CenterPoint thus recommended that a new subsection be added to new §18.3 that would implement the prohibition contemplated by the penalty schedule. To ensure that this obligation is harmonized with the Texas One Call Law, CenterPoint also suggested that the definition of an emergency in §18.2(3) be changed to match the corresponding definition in Texas Utilities Code, §251.155.

The Commission made the suggested change in the definition of "emergency" found in §18.2(3), but declines to add a new section to §18.3 at this time. The Commission has reconsidered its proposal to penalize the false reporting of an emergency locate request. The Commission has determined that, ultimately, it is within the purview of the Texas One Call Board to determine and enforce standards for emergency locate requests. The false emergency locate requests are clearly a resource issue for operators, but not of the same magnitude, in terms of safety, as failure to locate, failure to make a positive response, or failure to give notice of intent to excavate. The Commission has removed the penalty proposed in Table 1, line 2.

CoServ observed that the proposal details locate request procedures that cannot be easily explained on the request. It also requires that a copy of the locate ticket be at each excavation site or be provided within an hour of the request. The proposed rules also suggest that the positive response method be defined by the excavator. CoServ further commented that the proposal suggests all parties involved in a large project agree on protocols, such as ticket life and tolerance zone, but that there are too many parties involved with this type of locate request, making it difficult to agree on the protocols. CoServ suggested removing this language. Finally, CoServ agreed that it would like to have the locate request number on site, but did not think the rules should require that the actual ticket be on site. CoServ recalled that the Commission staff stated in a stakeholder meeting last year that the reason tickets should be on site is to prove the locate request was for the correct location. In CoServ's experience, most damages are not caused by incorrect ticket locations, and speculated that the Commission could be inundated with violations for not having the ticket on site. CoServ pointed out that CGA also recommends having the ticket number on site, not the actual ticket.

In response to CoServ's first comments, the Commission points out that the options for managing a construction site apply only to underground pipelines, which is the limit of the Commission's authority; therefore, the Commission declines to remove this language. With respect to CoServ's second comment, this matter was addressed in the third (and final) workshop, where the consensus was that prior to excavation, an excavator would be required to confirm that a copy of a valid locate ticket for the location was in the possession of the excavator's designated representative and could be obtained from the representative or could be provided within one hour of a request from the operator or the Commission. The designated representative may or may not be on site.

TxDOT commented that §18.3(a) through (d) place an unreasonable burden on TxDOT with regard to locating and marking

each test site. As stated previously, this would require 382,000 calls annually. In addition, the scope of work of many of TxDOT's archeological excavations is sometimes unknown until the work begins, due to the inherent exploratory nature of the work. Locating and marking each test site in order to comply with the proposed rules will create tremendous time delays and cause TxDOT to have to issue new archeological service contracts, or modify existing ones, all of which will negatively affect contractors, TxDOT staff, and ultimately the letting of needed highway construction projects.

In particular, TxDOT commented with respect to §18.3(a) and (d) and §18.7 of the proposed rules (which require that when the locality cannot be clearly described on a locate ticket, excavators must either mark excavation sites with paint or flagging prior to making a locate request, or meet with operators (there may be more than one) to establish protocols) that the existing statute (Texas Utilities Code, Chapter 251) does not require such marking or meetings. Because work conducted by TxDOT archeology and its contractors occurs all over the state, because localities are not readily described in the address-based format of a utility locate ticket, and because local TxDOT personnel do not have the expertise to predict specific excavation loci, the requirement to mark locations of individual excavations would necessitate a minimum of one extra field visit for each project.

The Commission disagrees with this comment; the rules do not require an excavator to use white-lining if the project can be described on a locate ticket. The rule provides guidelines to follow if white-lining is necessary. In addition, the exemption created for TxDOT in §18.1 should greatly reduce the impact on TxDOT's operations.

TGA commented that the rules should include wording that an excavator shall not call in an emergency locate if there is not an emergency. Although this is specified in other codes and referenced in Table 1, adding the definition of an emergency would put the information in this rule and make it clear under what circumstances an emergency locate would be appropriate. The Commission has reconsidered its proposal to penalize the false reporting of an emergency locate request. The Commission has determined that, ultimately, it is within the purview of the Texas One Call Board to determine and enforce standards for emergency locate requests. The false emergency locate requests are clearly a resource issue for operators, but not of the same magnitude, in terms of safety, as failure to locate, failure to make a positive response, or failure to give notice of intent to excavate. The Commission has removed the penalty proposed in Table 1, line 2.

The Coalition reiterated its comment regarding the use of the word "planned" with respect to excavation projects; the Commission agreed with the comment and has removed the word "planned" in adopted §18.2(17) and §18.3(a) and (d).

CenterPoint suggested adopting a new subsection (b) and renumbering the following subsections accordingly. CenterPoint's recommended new language would read as follows: *"An excavator shall notify a notification center or an operator of the existence of an emergency only when an emergency exists as defined in Section 18.2(3)"*. CenterPoint noted that this language would implement its recommendation that the rules prohibit falsely requesting an emergency locate to correspond to item no. 2 in the penalty schedule.

The Commission disagrees with this comment and declines to make the suggested change in the rule. The Commission has reconsidered its proposal to penalize the false reporting of an emergency locate request. The Commission has determined that, ultimately, it is within the purview of the Texas One Call Board to determine and enforce standards for emergency locate requests. The false emergency locate requests are clearly a resource issue for operators, but not of the same magnitude, in terms of safety, as failure to locate, failure to make a positive response, or failure to give notice of intent to excavate. The Commission has removed the penalty proposed in Table 1, line 2.

CoServ commented that "positive response" is not defined well in §18.3(b) as proposed. Under §18.3(b), an excavator must include in its notice how it would like to receive the positive response. This could result in unreasonable demands from excavators. The method should be defined as per CGA's Best Practices--documentation on the job site, callback, fax or automated response system. This would make the method uniform for all parties involved.

TGA commented that §18.3(b) should restate the means by which the positive response can be given. Although these means of positive response are covered in Texas Utilities Code, Chapter 251, the inclusion of the methods in this rule would clarify and facilitate determination of which means may be utilized to report said positive response.

OXY suggested that §18.3(b) be clarified as to how the excavator will receive an "all clear, no conflict" positive response. This would help clarify and be more consistent with 18.5. OXY is concerned with the excavator dictating the method in which he will receive a positive response. Methods should be specified to currently available and accepted methods while leaving the option open for approval of new methods should they be developed. Further, OXY recommended that an excavator who fails to provide working methods should be subject to penalties. For example, if a fax number is given but three documented efforts to send the fax have failed, the excavator would be in violation of the rule. The same should apply for an email that is non-deliverable or a telephone number that is not answered and there is no answering system.

The Coalition expressed concern with the manner in which operators will give the "positive response." Under §18.3(b) as proposed, pipeline operators will be required to give notification to an excavator confirming whether a pipeline facility is located near the area of excavation or whether the area is clear of an operator's facilities. As the rule is currently drafted, this notification is defined as "markings left at an excavation site, or other shared or transmitted information" in §18.2(17). In §18.3(b), excavators are required to include the method or methods by which the excavator receives the positive response. Furthermore, §18.5(a)(2) requires the pipeline operator to make the positive response in the manner in which the excavator specifies under §18.3(b).

The Coalition stated that while it is a strong supporter of positive response, it believed additional clarification is needed regarding the manner in which a positive response is to be given to an excavator. The proposed rule provided no parameters or limitations on the manner by which an operator may be required to provide a positive response. The Coalition respectfully requested that the definition of "positive response" in §18.2(17) (or another appropriate provision) be amended to include the words "by fax, telephone, e-mail, written correspondence or other methods approved by the Commission" in addition to the option of "markings left at an excavation site." The words "or other shared or transmitted information" could then be deleted. The Coalition argued

that this will provide several viable and specific options for which excavators can receive and document positive response notifications. The change would also permit the Commission to approve of other methods given extenuating circumstances, or as new methods of communication become available.

TxOGA suggested that §18.3(b) be clarified as to how the excavator will receive an "all clear, no conflict" positive response. This would clarify and be more consistent with §18.5. Pipeline operators are concerned with the excavator dictating the method in which he will receive a positive response. Methods should be specified to currently available and accepted methods while leaving the option open for approval of new methods should they be developed. TxOGA suggested that positive response be limited to responding by telephone, fax, e-mail, or letter.

In response to the comments by CoServ, TGA, OXY, the Coalition, and TxOGA, the Commission notes that the manner of providing a positive response was the subject of lengthy discussions in the workshops. While there was no general consensus, the discussions did reveal that this issue demands both specificity and flexibility. To meet those requirements, the Commission adopts new §18.2(17) with clarifying changes. As adopted, the definition of "positive response" will mean markings left at an excavation site, fax, phone, e-mail, pager, or written correspondence. The phrase "other shared or transmitted information" has been deleted, and the phrase "other methods approved by the Commission" is not included to make it clear that only the specified methods may be used. The new rules impose an affirmative duty on both excavators and operators to communicate clearly and directly with each other.

TxDOT commented that even though §18.3(b) references a positive response requirement, there is no positive response provision in the current Texas One Call Rules (Texas Utilities Code, Chapter 251). The Commission disagrees with this comment; the Commission does not have authority to implement or administer Texas Utilities Code, Chapter 251. The Commission is, however, implementing and will administer its own, separate statutory authority pursuant to Texas Natural Resources Code, §117.012, and Texas Utilities Code, §121.201 (as amended by House Bill 2161, Acts 2005, 79th Leg., R.S., ch. 267, §§6 and 13, eff. Sept. 1, 2005), and Texas Health and Safety Code, §756.106 (as added by Senate Bill 9, Acts 2005, 79th Leg., R. S., ch. 1337, §19, and editorially renumbered as Health and Safety Code, §756.126). The Commission is adopting the most significant national Best Practices in these rules, one of which is the requirement that pipeline operators make a positive response.

With respect to new §18.3(c), CenterPoint recommended deleting the language of proposed subsection (c) and substituting the following: *"The excavator shall identify the excavation site by providing the following information in its notice to the notification center under subsection (a).*

"(A) (i) the street address, if available, or

"(ii) if there is no street address, an accurate description of the excavation area using any available designations such as the closest street, road or intersection, including GPS coordinates if available or

"(iii) request a meeting with the underground facility operator to establish a protocol under Subsection (d) of this rule; and

"(B) the location of the excavation at the address or excavation area by reference to structures, roads, easements, or other known points of reference. In lieu of such a description, an excavator shall indicate in the notice that it will white-line the excavation area in accordance with this rule or will provide such a description at a meeting with the operator."

CenterPoint stated that this language was originally developed in the Texas Common Ground effort and recognizes that an operator needs two sets of information about the location of a proposed excavation. It first needs to know the general street address or other general location of the excavation and then a more specific description of the location of the excavation at the address or excavation area. In many cases, it will not be necessary for an excavator to white-line in order to adequately identify the location at an address. Current practice allows an excavator to identify the excavation location by reference to an easement, street, or other point of reference. Only when this information is insufficient should the excavator be required to white-line. (A corresponding change reflecting this policy was also proposed in CenterPoint's comments on new §18.7.)

The Commission disagrees with this comment. The contents of locate tickets are not within the authority of the Commission. The Texas One Call program has guidelines for use by the notification centers, and the Commission has determined that it would be counterproductive to adopt rules that are inconsistent with practices that are fairly well established.

CenterPoint further commented that while both the Texas One Call Law (Texas Utilities Code, Chapter 251) as well as the Commission's proposed rules require an excavator to identify the location of a proposed excavation by providing certain specific information, neither regulatory scheme currently imposes a limit on the size of the area that can be included in one ticket. In many cases, tickets are called in for areas that are so large that the ticket cannot be practically located within the 48-hour time limit. In other cases, the location information is not specific enough, though white-lining can clarify any ambiguity.

CenterPoint understands that the Texas One Call Board is considering a change to the technical standards for notification centers that would limit the size of the area that could be included on one ticket. This change could alleviate some of these hardships. The Commission's proposed rules recognize the need for even more definition in cases of large excavations by requiring that excavators and operators enter into protocols to further define the marking process for such projects (proposed §18.3 and §18.10). Those two rules should require that the protocols include a schedule of the contractor's work so that the operator may phase its marking work to match the progress of the excavation. CenterPoint suggested language implementing this requirement in its comments to the proposed rules §18.3 and 18.10. The Commission agrees with these suggestions and has implemented these changes in the adopted rules.

With respect to §18.3(d), CenterPoint suggested inserting a new paragraph (4) in subsection (d), to read as follows: *"the schedule of work on the excavation and the chronological order in which applicable locate tickets are to be marked."* The Commission agrees with this suggestion and has made this change in the adopted language of the rule.

TxDOT recommended that alternate methods to a face-to-face meeting be allowed since arranging face-to-face meetings in very rural areas would prove difficult. Section 18.3(a) and (d) and §18.7 of the proposed rules require that when the locality cannot be clearly described on a locate ticket, excavators must either mark excavation sites with paint or flagging prior to making a locate request, or meet with operators (there may be more

than one) to establish protocols. The existing statute (Texas Utilities Code, Chapter 251) does not require such marking or meetings. Because work conducted by TxDOT archeology and its contractors occurs all over the state, because localities are not readily described in the address-based format of a utility locate ticket, and because local TxDOT personnel do not have the expertise to predict specific excavation loci, the requirement to mark locations of individual excavations would necessitate a minimum of one extra field visit for each project.

The Commission disagrees with this suggestion, because it is unnecessary. The provisions of new §18.9 would permit TxDOT and an operator to agree on an alternative method for discussing the excavation activities and establishing protocols. Also, the Commission has no authority to implement or administer Texas Utilities Code, Chapter 251. The Commission is, however, implementing and will administer its own, separate statutory authority, as previously stated. Additionally, the exemptions adopted for specific TxDOT operations in new §18.1(d) should mitigate any undue burden on TxDOT.

The Coalition also sought clarification with regard to a project described as "too large" under §18.3(d). As it is currently written, the rule is very ambiguous with regard to the characteristics of a project that is "too large to mark using white-lining or is so extensive that a full description cannot be provided on a line locate ticket." The Coalition requested that a specific project size be outlined in the rule, and suggested that a project be deemed "too large" if it exceeds one mile in length or width.

The Commission disagrees with the suggestion to specify a project size as being "too large," because every project is different and it is likely that some projects smaller than one mile in length or width would still be impossible to describe clearly and completely on one locate ticket. The new rules impose an affirmative duty on both excavators and operators to communicate clearly and directly with each other, and if the excavator's project description is ambiguous to the operator, the operator must seek clarification.

TxDOT objected to the requirement in new §18.3(e) and (f) that would require the excavator to "refresh" the ticket every 14 days while excavation is ongoing. The existing statute (as interpreted under Texas Attorney General Opinion No. JC-0234) does not require "refreshing" the locate ticket every 14 days if excavation is ongoing. This new requirement will further increase the cost of fulfilling TxDOT's archeological excavation duties.

The Commission disagrees with TxDOT's comment, because the Commission is not implementing Texas Utilities Code, Chapter 251. Additionally, as adopted with clarifying amendments, §18.3(e) will limit the request to refresh to the area yet to be excavated, which the Commission views as consonant with Texas Attorney General Opinion No. JC-0234. New §18.9(a)(6) permits an excavator and operator to jointly agree on the life of a locate ticket and the circumstances that require refreshing the locate ticket. Finally, the exemption established for TxDOT's archeological duties should greatly reduce if not eliminate any undue burden.

TGA commented that the request to refresh should be only for the area that has not been excavated. The utilization of a refresh of the original locate ticket information results in the locator performing not only duplicate locates on areas already located, but also on areas already excavated and backfilled. The relocation a pipeline in an area of completed excavation would have no value in protecting the pipeline, unless the excavator plans to return to this area. The recommended language is: *"A request to refresh shall be limited to the area yet to be excavated."*

The Coalition also suggested that in §18.3(e) the word "may" should be changed to "shall." The justification for this is primarily cost, especially for large projects. If an excavation project is partially complete after the initial, or subsequent, intervals of 14 days, an operator should be required to mark only the area where excavation has yet to occur. Some large projects go on for months. If an operator has to needlessly re-mark all the areas of the project, it has the potential of being costly in terms of employee time and resources. Furthermore, re-marking only the area in which excavation will still occur reduces the amount of confusion regarding the completed and non-completed parts of the project. By requiring only the portion of the project that has not been completed, it saves all stakeholders time, money and resources.

The Commission agrees with these comments and has adopted new §18.3(e) with the suggested change in wording from "may" to "shall."

With respect to new §18.3(f), which would permit an excavator and an operator to agree that the life of a line locate ticket is more than 14 days, provided that certain conditions are met, Air Products recommended that the wording be changed to "14 working days." CoServ also commented that the proposed rules define the ticket life as 14 working days; however, the rest of the document says 14 days. Where each instance ticket life is mentioned in the rules it should state 14 *working* days. This will prevent confusion to all parties who must follow these rules.

The Commission disagrees with this suggestion; as adopted, the general provision in §18.1(g) states that unless otherwise specified, all time periods that are stated in days shall mean working days.

Marathon recommended deleting the option in §18.3(f) for extending the ticket life. The ticket should be renewed or another ticket should be required to extend the excavation activities. With a definite ticket life, reminder systems can be employed to verify the project is complete or to note that more monitoring necessary. In Marathon's view, a variable ticket life makes project management much more difficult. The Commission declines to make this change; if Marathon prefers a definite ticket life, then it can adopt a company policy not to agree to extend the standard 14 working day period.

Regarding §18.3(g), which requires both the excavator and the operator to retain a copy of any agreement made pursuant to §18.3(f) to extend the life of a locate ticket, TxDOT recommended clarifying the length of the period required to retain the agreement. The Commission declines to make this change. The general provision in §18.1(i) requires a minimum of four years for retention; however, other specific events, such as pending or ongoing litigation, may compel a longer retention period. In addition, TxDOT's own state agency records retention policy may govern the retention period for such documents.

With respect to §18.4, CoServ suggested that excavators follow CGA's Best Practices, which states "the route of the excavation is marked with white paint, flags, stakes or a combination of these to outline the dig site prior to notifying the one call center and before the locator arrives on the job site." The Commission disagrees that this particular change needs to be made. The new rules in Chapter 18 incorporate many of the Best Practices, but they are found in separate rules because they are more detailed than in the Best Practices. The Commission appreciates

CoServ's commitment to following the recommended Best Practices, and looks forward to continued collaboration with CoServ as the Commission incorporates additional national Best Practices standards into Chapter 18.

TxDOT commented that §18.4(a) through (f) place an unreasonable burden on TxDOT with regard to confirming the location of a pipeline. While TxDOT recognized that all pipeline locations are not known or mapped correctly, this new set of procedures will significantly delay and restrict TxDOT's ability to build and maintain highways. The Commission finds that the exemptions for specified TxDOT activities adopted in §18.1(d) will, to a significant degree, remove any undue burden on TxDOT that would otherwise have been imposed.

PHMSA commented that the obligations of the excavator to avoid damage to underground pipelines contained in §18.4 appear to prohibit blind reliance on the one call and marking processes. PHMSA expressly endorses the obligation to observe site conditions and act accordingly. The Commission agrees with PHMSA's comment.

Atmos commented regarding the requirement in §18.4(c) that a copy of the locate ticket be on-site with the excavator or be available within one hour. Atmos noted that for emergency locate requests, the requestor is typically on site and will not have the ability to have a locate ticket printed or receive a copy of the ticket electronically. While Atmos supports the requirement for an excavator to have a copy of the locate ticket on-site, Atmos suggested that for emergency locates, it is appropriate for the excavator to simply have the assigned locate number available on-site. Because the proposed language was the general consensus product of the workshop discussions, the Commission disagrees with this comment and finds there is no need to make the suggested change.

Gary W. Craig commented regarding the requirement that each excavator must have a paper copy of each locate ticket on site. That currently is over two million locate request pages. Mr. Craig believes the best practice would be to require the excavator to have the locate number. The Commission disagrees with this comment, because it appears to refer to an early draft version of §18.4(c). In the proposed version published in the *Texas Register*, there is an alternative method for complying, which is that the valid locate ticket can be provided within one hour of a request from the operator or the Commission.

TxDOT commented, regarding §18.4(c), that allowing only one hour to produce a valid locate ticket is too short. If the locate tickets are kept in a central office it may take longer to get the ticket to the operator. For example, if the office is closed for lunch or after hours, it could be impossible to produce a locate ticket within the proposed required one-hour window. The Commission finds that the exemptions adopted in §18.1(d) for the specified TxDOT activities will likely reduce or eliminate any undue burden on TxDOT operations.

API and AOPL commented with respect to §18.4(d), which describes various above-ground indications of an underground pipeline, that two additional indications should be included: the presence of "fence posts" painted in colors typically used to mark underground pipelines (predominantly orange and yellow), and the presence of rectifier units, which are box-shaped devices, typically pole-mounted on or near a pipeline right-of-way, used to provide cathodic protection to most steel underground pipelines. Both such indications occur with regularity along most underground pipeline rights-of-way and are readily observable.

CenterPoint suggested inserting the phrase "meter sets" after "above-ground pipeline valves" in §18.4(d). This change points out that the presence of a natural gas meter at a residence is sufficient notice to an excavator of the presence of an operator line leading up to the meter that should be marked.

The Coalition also wanted the Commission to amend §18.4(d) upon adoption. During the public workshops and informal comment period, AGC of Texas addressed how an excavator should check for unmarked pipelines prior to excavation. A sentence was added to the proposed rule that identified several pipeline apparatuses that can signify an underground pipeline is located in an area. The Coalition agreed with the examples identified in the proposed rule, but recommended that the list be prefaced with the condition that checking for unmarked underground pipelines includes, *but is not limited to*, looking for additional pipeline markers, aboveground pipeline valves and regulator stations. This change would clarify that the identification methods are not the only indications that a pipeline may be in the vicinity of the excavation.

In response to API and AOPL, CenterPoint, and the Coalition, the Commission notes that it did not intend for the items in §18.4(d) to be an exhaustive list of above-ground indications of the presence of an underground pipeline, only examples. The Commission agrees that these items suggested by CenterPoint and API and AOPL are common indicators of the presence of an underground pipeline, and has included them in the adopted rule. The Commission also agrees that the condition suggested by the Coalition accurately conveys the Commission's position that the list comprises examples only and is not a complete list of the clues that might indicate the presence of an underground pipeline.

TxDOT recommended adding in §18.4(d) that the excavator shall make a visual check. The Commission agrees that this adds a useful degree of specificity to the provision, and has added the suggested wording.

Air Products suggested that §18.4(e) be amended to remove the prohibition that an excavator not begin excavating until a second notice is given if any of the conditions listed in paragraphs (1) through (4) obtain. Air Products suggested that the provisions would simply read that it is considered good practice for an excavator to make the second call in those situations. The Commission disagrees with this comment. Paragraphs (1) through (4) describe situations in which there is either conflicting or obviously erroneous information about the presence of an underground pipeline. Thus, these would be clear indications that it is not safe to begin excavation. The Commission makes no change to this section based on Air Products' comment. Air Products also suggested adding "or" after paragraphs (1) and (2) in subsection (e), which the Commission considers unnecessary.

TxDOT recommended deleting §18.4(e)(3) because the operator should make a positive response, and the excavator should not be held up because the operator failed to perform. The Commission agrees that an operator should make a positive response, but the Commission disagrees that this provision should be removed. The waiting time on a second call is only four hours, which the Commission considers to be minimal in the context of greater safety. Further, the exemptions crafted for TxDOT operations should significantly reduce or eliminate any undue burden on TxDOT.

Regarding §18.4(f), CenterPoint suggested rewording it to refer to subsection (e) of §18.4, rather than to §18.3, and to add a re-

quirement that an excavator report an operator's failure to make a positive response within four hours of a second call. The subsection would read as follows: *"If an excavator has given a second notice in accordance with subsection (e) of this section and there is no positive response within four hours, the excavator may begin excavating. The excavator shall also report that fact to the Commission through TDRF as set forth in §18.11 of this title, relating to reporting requirements."* The Commission agrees with this recommendation because it clarifies the procedure on the second call requirement, and if an operator fails to respond, both should be reported. However, the Commission finds that the more appropriate location for the clarification regarding the reporting requirements is in new §18.5(c) and §18.11(c), which are adopted with revised wording.

CoServ made comments about several rules regarding line markings, including preservation and method. Regarding §18.4(g), which states that the excavator must protect and preserve locate markings from start to finish of the project, CoServ observed that line markings are destroyed during most excavations, and asking an excavator to preserve the marking is not reasonable. The Commission points out that these rules do contain many of the CGA Best Practices standards, although they are arranged somewhat differently. However, the Commission must point out that it is up to the operator (and its locator) to mark or re-mark line locations, if that becomes necessary, with condition-appropriate materials. The Commission agrees that it may indeed be necessary to re-mark every day to meet the expected standard, which is a performance measure, not a "command-and-control" directive.

Finally, the Commission adopts a new subsection (h) in new §18.4, which incorporates comments made with respect to new §18.11, relating to reporting requirements. The Commission intends for §18.11 to be the guidance for how pipeline damage reports are made to the Commission; however, many of the comments suggested that the Commission adopt a requirement that an excavator that damages a pipeline should notify the pipeline before filing a report with the Commission. The Commission agrees that it is prudent for an excavator to take the appropriate steps in the event of a damage incident, but finds that new §18.4, relating to excavator obligation to avoid damage to underground pipelines, is also a good location for that requirement. As adopted, new §18.11(b) and new subsection §18.4(h) require that each excavator that damages an underground pipeline shall notify the operator of the damage through the notification center immediately but not later than two hours following the damage incident. New §18.4(h) also provides that an excavator that damages an underground pipeline may not cover the exposed pipeline without approval of the operator.

Atmos commented on §18.5(a), which provides that an operator should provide positive response to an excavator within the time frames of Texas Utilities Code, Chapter 251. Atmos commented that the positive response process should not diminish the time in which an operator has to locate its facilities. In other words, if an operator has 48 hours to mark its facilities under Texas Utilities Code, Chapter 251, then §18.5 should not reduce that statutory time frame by requiring that both the marking and the positive response occur within that time frame. Atmos suggested that §18.5(a) be revised to require positive response be provided within 3 hours following the expiration of the time frames specified in Texas Utilities Code, Chapter 251.

The Commission disagrees. Both the positive response and the line location marking should occur within the 48 hours allowed by Texas Utilities Code, Chapter 251. Even if an operator needs the full 48 hours to locate and mark the pipeline, it should not take another three hours to provide the positive response notice back to the excavator.

TxDOT pointed out that there are no positive response requirements in the Texas Utilities Code, Chapter 251. The Commission is not adopting these rules pursuant to that statutory provision; imposing a requirement for a positive response does not conflict with practices under Texas Utilities Code, Chapter 251.

Air Products commented that §18.5(b) should include the following statement regarding retention of positive response records: *"This record may be in the form of an electronic record at the Notification Center."* The Commission disagrees with this comment and declines to make the suggested change because the Commission has no authority to require the notification centers to retain records of any kind.

CenterPoint recommended that §18.5(c) be deleted to be consistent with CenterPoint's proposal that a report to the Commission should be required only upon an operator's failure to respond to a second notice. The Commission disagrees with this comment because the Commission wants reports of all failures to give a positive response. The Commission has added the specific requirement to report a second failure to give a positive response to §18.5(c) as a clarifying change. The Commission has also made this clarifying change in §18.11(c).

TxDOT recommended revising the wording of §18.5(c) to read as follows: "An excavator that *experiences an operator failing* to provide a positive response to an excavator shall report that fact to the Commission through TDRF as set forth in §18.11 of this title, relating to Reporting Requirements." The Commission disagrees this changed wording clarifies the provision, and has made no change.

CoServ criticized the requirement in §18.6 that markings should be valid for 14 days because the provision does not state how this should be accomplished. Weather and other outside conditions can change the validity of the locates. CGA's Best Practices states "the excavator protects and preserves the staking, marking or other designations for underground facilities until not longer required for proper and safe excavation. The excavator stops excavating and notifies the one-call center for re-marks if any facility mark is removed or no longer visible."

The Commission points out that these rules do contain many of the CGA Best Practices standards, although they are arranged somewhat differently. However, the Commission must point out that it is up to the operator (and its locator) to mark or re-mark (if that becomes necessary) line locations with condition-appropriate materials. The Commission agrees that it may indeed be necessary to re-mark every day to meet the expected standard, which is a performance measure, not a "command-and-control" directive.

TxDOT recommended revising §18.6(b) so that it reads as follows: "If a line locate ticket has been refreshed pursuant to §18.3(e) of this title, relating to Excavator Notice to Notification Center, then the operator shall either ensure that markings are still *visible* or shall re-mark." The Commission agrees that this standard can be made clearer, but has made a slightly different change to this subsection than was suggested by TxDOT. Instead of substituting "visible" for the proposed word "valid," the Commission has added the visibility requirement. The revised wording reads: "If a line locate ticket has been refreshed pursuant to §18.3(e) of this title, relating to Excavator Notice to

Notification Center, then the operator shall either ensure that markings are still *visible and* valid or shall re-mark."

CenterPoint suggested amending §18.6(c) to change "is considered damaging to" to "may permanently damage" because it provides a more objective standard for determining when spot marking or other methods should be used in sensitive areas. The Commission agrees with this suggestion and has adopted §18.6(c) with this change.

TxDOT commented that §18.6(c) does not make clear who shall determine that a line marking is damaging to property. The Commission agrees, but notes that because the locator will be marking the pipeline locations, it is the locator who will make the decision about how to mark. In most situations, however, it is likely that the construction contractor would make any repairs requested by the property owner or buyer. The Commission finds that the clarifying change adopted in response to CenterPoint's comment does provide a more objective standard for this requirement.

AGC of Texas expressed its belief that §18.7(a) does not mandate that in all circumstances an excavator must mark the specific area of excavation using white paint, flags, or stakes, but, rather, intends that "white-lining" by an excavator be used only according to §18.3(c), "when an excavation site cannot be clearly identified and described on a line locate ticket." AGC commented that the intent of this requirement would be more clearly understood if §18.7(a) were to read as follows: *"(a) Prior to giving notice pursuant to 18.3 of this title, relating to Excavator Notice to Notification Center, an excavator shall mark (if applicable according to 18.3 (c)) the specific excavation area using white paint, flags, or stakes, whichever is most visible for the terrain."*

Atmos observed that proposed §18.7 provides that prior to giving notice of an intent to excavate, an excavator is to mark the area of intended excavation with white paint, flags, or stakes, but on the other hand, proposed §18.3 provides that if an excavator can clearly identify the excavation site on the locate ticket, no on-site marking is necessary. Atmos supports the §18.3 approach and suggested that §18.7 be revised to limit the white-lining requirement to instances in which the proposed excavation area cannot be clearly identified and described on a line locate ticket.

CenterPoint also suggested that §18.7(a) be amended to clarify the situations in which white-lining must be used. The Commission agrees with the comments of AGC of Texas, Atmos, and CenterPoint regarding the need to clarify the way in which §18.3 works with §18.7, and has adopted §18.7(a) with the clarifying language suggested by AGC of Texas.

TxDOT recommended revising the title of §18.7 to "Excavator Marking Requirements *if White-Lining is Used*" since not all notifications require "white-lining." Sections 18.3(a) and (d) and 18.7 of the proposed rules require that when the locality cannot be clearly described on a locate ticket, excavators must either mark excavation sites with paint or flagging prior to making a locate request, or meet with operators (there may be more than one) to establish protocols. The existing statute (Texas Utilities Code, Chapter 251) does not require such marking or meetings. Because work conducted by TxDOT archeology and its contractors occurs all over the state, because localities are not readily described in the address-based format of a utility locate ticket, and because local TxDOT personnel do not have the expertise to predict specific excavation loci, the requirement to mark locations of individual excavations would necessitate a minimum of one extra field visit for each project.

The Commission finds that adopting the new rules in Chapter 18, which are adopted under statutory authority previously cited, does not conflict with the existing provisions in Texas Utilities Code, Chapter 251. Further, the exemptions adopted for specified TxDOT activities should reduce or eliminate any undue burden on TxDOT.

Atmos noted that §18.8 provides in part that a locator needs to make a reasonable effort to advise the excavator if the locator, while marking the facility, discovers customer-owned underground piping. Atmos seeks clarification on what constitutes a reasonable effort to advise the excavator. For example, if a locate ticket is for a back yard and the gas meter is an alley set, then customer-owned gas piping likely runs through the back yard. Atmos asked whether a locator can simply leave a uniquely colored flag that the notes "possible customer owned piping," or whether the locator must create an electronic positive response noting "possible customer owned piping," or take other action. Atmos stated that this obligation should be clarified by the Commission in the final rule. In addition, Atmos noted that the proposed regulation is silent on the method for providing an "all clear" on-site positive response. Atmos recommended that language should be added in a new subsection indicating how an "all clear" positive response should be provided by on-site markings.

The Commission points out that an operator will know how an excavator wants to be notified of a positive response, pursuant to §18.3(b). In addition, an operator and an excavator might recognize, with respect to a particular project, that there is a high likelihood of discovering customer-owned underground piping and establish protocols applicable to that excavation site. In particular, the operator and excavator could agree on the mode or modes of communication among the entities working at an excavation site, e.g., telephone or other electronic means or face-to-face meetings at prescribed times or intervals. The Commission expects that operators will use common sense and good judgment regarding methods of communication with excavators, and declines to make changes in §18.8.

CenterPoint suggested adding a sentence in §18.8(a) to read: *"An underground pipeline shall be considered accurately marked if the entire width of the pipeline is within the tolerance zone created by the marks."* CenterPoint commented that the additional language more clearly defines when a line will be considered accurately marked. TGA commented that §18.8(a) should include a definition of an accurate mark, and suggested substantially the same wording that CenterPoint offered.

The Commission disagrees with these comments. The marks do not delineate the tolerance zone. Marking identifies the approximate center line of an underground pipeline. The Commission urges operators to establish good communication with excavators and to use the provisions of new §18.9 to establish site-specific protocols with respect to excavation activities and/or marking requirements that will or will tend to ensure the proper and safe excavation in the vicinity of an underground pipeline.

TxDOT restated its recommendation regarding vertical locations of underground pipelines, and recommended revising §18.8(b) to read: "Locators shall mark the approximate center line of an underground pipeline *including indicating a depth-of-cover. These marks shall be within the tolerance zone*." The Commission disagrees with the recommendation to include vertical locations at this time, because the technology is still emerging, its use is not widespread, and the results are still too variable to be reliable.

AGC of Texas commented that the language in §18.8(c) leaves the excavator exposed to the possibility of damaging an underground utility if the excavator is not informed in some verifiable manner of the existence of a customer-owned underground pipeline. AGC of Texas requested that, at a minimum, a locator should be required to mark the pipeline. In addition, a definition of a "customer-owned underground pipeline" would be beneficial. The Commission disagrees with these comments, and notes that this issue was discussed extensively at the workshops; none of the participants agreed with the more stringent standard recommended by AGC of Texas. It is because customer-owned pipeline is not owned by the operator that it cannot be marked by the locator, but it is prudent for the operator to inform the excavator of the likelihood of its presence. The excavator is certainly not limited to relying solely on an operator's suggestion as to the existence of customer-owned pipeline; an excavator may certainly elect to communicate directly with the customer to learn more information about possible underground pipeline that is not part of the operator's facilities.

CenterPoint recommended inserting the following phrase at the end of §18.8(c): *"but is not required to mark the customer owned line accurately."* This additional wording clarifies that the "reasonable effort" to advise an excavator of the presence of a customer-owned line does not require any marking of that line as contemplated under the rules. The Commission disagrees that this additional wording is necessary. The only requirement in subsection (c) is that the operator make a reasonable effort to inform the excavator of the presence of customer-owned underground pipeline.

CoServ commented that subsection (c) does not address what the excavator should do once it has knowledge of the presence of the line. Most builders do not make owners aware of their obligation regarding their gas lines. CoServ asserted that the excavator should be responsible for working with the owner protecting this line. This should not be the responsibility of the locator or utility. The gas is measured and does not fall under TxDOT or Commission rules. The Commission reiterates that the only requirement in subsection (c) is that the operator make a reasonable effort to inform the excavator of the presence of customer-owned underground pipeline. The excavator is not limited to relying solely on an operator's suggestion as to the existence of customer-owned pipeline; an excavator may certainly elect to communicate directly with the customer to learn more information about possible underground pipeline that is not part of the operator's facilities.

TxDOT recommended providing a definition of "reasonable effort" in §18.8(c). The Commission finds that this is not necessary at this point, and declines to make a change to this subsection.

TxDOT commented, regarding §18.8(d), that the markings in question should be known to the operator. The Commission is not clear what this comment means and is unable to respond.

CoServ commented regarding the requirement in §18.8(e) that a locator must mark the pipeline "by means of stakes, paint, flags or a combination of two or more of these." CoServ commented that using a combination of two markings would be difficult or impossible when marking concrete, and that CGA's Best Practices suggests "one or any combination of the following: paint, chalk, flags, stakes, brushes or offsets."

The Commission points out that §18.8(e) does not require the use of two methods to mark a pipeline location. The rule requires use of either one of the methods listed (stakes or paint or flags) or a combination of two or more of them. If the locator is marking concrete, then it is likely that only paint will work. The remainder of the text in this subsection makes it clear that the choice of marking medium will depend on the terrain, site conditions, and type and extent of the proposed excavation.

The Coalition suggested changes to §18.8(f), specifically with regard to the required marking intervals. Under the proposed rule, an operator is required to mark the location and direction of a pipeline using marks not further than 20 feet apart. The Coalition suggested an alternative marking structure that takes into account the location of excavation activities in the vicinity of an existing underground pipeline. The Coalition requested that a pipeline operator be required to mark the location of pipeline that will be impacted by excavation activity that will cross a pipeline facility. Under this alternative, for any excavation activity that parallels an existing underground pipeline, the operator would be required, if feasible, to temporarily mark the location and direction of an existing underground pipeline at 10 foot intervals if the excavation is 10 feet or less from the pipeline, or at 50 foot intervals if the distance of the excavation is greater than 10 feet from the existing underground pipeline. The Coalition's suggested wording reads as follows: *"(f) A locator shall mark at sufficient intervals to indicate clearly the approximate horizontal location and direction of the underground pipeline or pipelines. The distance between any two marks indicating the same line shall not exceed 10 foot increments when excavation will occur within 10 feet of a parallel underground pipeline. Markings shall not exceed 50-foot increments for excavation occurring greater than 10 feet, but not greater than 25 feet, parallel to the pipeline. A shorter distance between marks may be necessary because of site conditions or directional changes of the underground pipeline."*

API and AOPL also commented with respect to §18.8(f), which prescribes a maximum 20-foot distance between marks used to indicate the location of an underground pipeline, and further providing that markings should be placed at shorter intervals due to site conditions or directional changes in the pipeline. Contrary to the comments of the Coalition, API and AOPL commented that encroachments to a pipeline facility may yet occur even when an excavation is more than 10 feet away from an underground pipeline. API and AOPL encouraged the Commission to consider prescribing that the distance between marks be proportional to the distance of an excavation from the underground pipeline up to a maximum of 50 feet between marks for an excavation that is 50 or more feet distant from the pipeline. In that manner, the closer an excavation is to an underground pipeline, the more closely marks would be placed, out to the 50-foot distance and beyond, at which point marks would, in most cases, be no more than 50 feet apart. API and AOPL encouraged the Commission to retain the general requirement of shorter distances between marks due to site conditions other than distance and due to directional changes in the underground pipeline.

The Commission disagrees with the changes suggested by both the Coalition and API and AOPL. This is a straightforward standard and easy to follow. An operator and an excavator can use §18.9 to agree on a different marking protocol.

TxDOT recommended revising §18.8(f) so that it would read: "A locator shall mark at sufficient intervals to indicate clearly the approximate horizontal *and vertical* location and direction of the underground pipeline or pipelines." The Commission disagrees with the recommendation to include vertical locations at this time, because the technology is still emerging, its use is not widespread, and the results are still too variable to be reliable.

OXY commented on §18.8(g), which requires a designation of pipe size when the pipe is greater than six inches, which OXY believes supports this suggestion. The implied assumption is that the center line of the pipe is marked. However, reality is that the probing, tagging, and associated marking may actually be somewhere between the center line and the edge of the pipe. Allowing for a reasonable designation by the pipeline operator should help protect a pipeline with a diameter greater than 36 inches. OXY commented that half the diameter plus 18 inches would only equal the diameter of the pipe and be less than the diameter of a 40-inch pipe. OXY stated that this definition appears to be in conflict with §18.9(a)(7) (adopted as §18.9(a)(8)), which states that a tolerance zone cannot be less than 24 inches. Adding the proposed language to the definition of "tolerance zone" (*"or as reasonably designated by the pipeline operator to allow for protection of large size pipes or as agreed to in a writing between the excavator and the operator"*) would clarify the tolerance zone under project agreements.

The Commission disagrees with the premise of this comment. The Commission agrees that the marking requirement applies to the approximate center line of the pipeline, and recognizes that the markings will fall somewhere between the center and the edge of the pipeline. However, the reason for requiring that markings of an underground pipeline greater than six inches in nominal outside dimension must include the size in inches at every other mark is so that the tolerance zone can be observed by the excavator during excavation, because it is within the tolerance zone that the requirements of §18.10 come into play. The tolerance zone is not half the diameter of the pipe plus 18 inches, as OXY commented. The tolerance zone is half the diameter of the pipeline plus a minimum of 18 inches on either side of the outside edge of the underground pipeline on a horizontal plane.

The Commission does agree with OXY that the provision in §18.9(a)(8) (which was proposed as §18.9(a)(7)) regarding a minimum tolerance zone is inconsistent with the definition in §18.2(17). The Commission adopts §18.9(a)(8) with the conforming clarifying change.

AGC of Texas requested that the following language to be added to §18.8 as a new subsection (j) to better define an improper locate. *"(j) If a pipeline is found to be outside of the tolerance zone, as established from the marked location, then the operator is considered to have failed to mark the pipeline properly and is subject to the appropriate penalty."* The Commission disagrees that this additional language is needed at this time, because the issue of whether an underground pipeline is properly located and/or marked is likely to be the subject of an enforcement action.

SM&P commented that §18.9 fails to recognize that on many occasions more than two parties may be involved in an excavation site and mutual agreement, although desirable, may not be obtainable. The competing interests may not have mutual interests in time lines and workforce availability. SM&P believes this language should be removed from the Commission's proposed rules as it risks potentially dangerous conflict between parties rather than promoting cooperation and public safety. The Commission recognizes that the more entities that are involved in any project, the more complicated it becomes to arrive at agreements. However, the Commission disagrees that §18.9 should be removed. The only participants in any excavation project that the Commission has authority over are the pipeline operator and the excavator. It is only to those two entities that the provisions of §18.9 pertain. Certainly, operators and excavators must work with other entities, but this rule does not apply to those others.

TxDOT commented, regarding §18.9(a)(4), that the reason for the requirement to provide ownership is not clear. The Commission is making a distinction between ownership of a locate ticket, which is typically the entity making the call to the notification center, and possession of a locate ticket, which could be any party, as they may elect. It is also possible that, on projects where there is more than one excavator, the parties, by agreement, could provide for only one excavator to make the call to the notification center. This, in turn, would necessitate that there be some agreement regarding ownership of that locate ticket. Again, this rule is only an option for participants to manage an excavation project as efficiently as possible, given the myriad variations that may be presented in excavation projects.

CenterPoint wanted to insert a new paragraph (7) in §18.9(a) and renumber the following paragraphs accordingly. The new paragraph would read: *"state the schedule of work on the excavation and, if applicable, the chronological order in which applicable locate tickets are to be located."* The Commission agrees that this is a helpful addition, and has adopted §18.9(a) with the amended wording.

Air Products suggested amending §18.9(a)(7) (adopted as §18.9(a)(8)) to allow a tolerance zone to be defined by operator easement privileges. The Commission disagrees with this suggestion; easements are not sufficiently accurate to be used in defining a tolerance zone for excavation in the vicinity of an underground pipeline.

Atmos commented with respect to §18.9(a)(7) (adopted as §18.9(a)(8)) that the minimum tolerance zone detailed in this section is 24 inches, without specifying that that is on either side of the pipe, while "tolerance zone" is defined in §18.2(17) as 18 inches on either side of the outside edge of the pipe. Atmos submitted that to eliminate confusion, a consistent standard should be used and proposed that the 18-inch parameter detailed in §18.2(17) be used in §18.9(a)(7) (adopted as §18.9(a)(8)). The Commission acknowledges the discrepancy, and has made the change in §18.9(a)(8) as adopted.

CoServ commented regarding the requirement that when excavation is to take place in a tolerance zone, reasonable excavation practices such as hand digging, soft digging, vacuum excavation and pneumatic methods, or mechanical and technical methods approved by the operator should be followed. The tolerance zone is proposed to be defined as half the width of the underground pipeline plus a minimum of 18 inches on either side of the outside edge of the underground pipeline on a horizontal plane. CoServ commented that while reasonable excavation practices within tolerance zones, as stated above, are appropriate for third-party excavators, it may be impractical for operators and operator contractors exposing their own pipes. The cost of excavation of CoServ pipe by CoServ's own crews will increase significantly if CoServ is required to use hand digging or vacuum methods. CoServ suggested that mechanical methods be left in as an approved method for operator crews and operator contractors.

The Commission points out that in excavating in a tolerance zone, new §18.10(b) does not mandate hand digging. The basic requirement of the rule is to use "reasonable care." The rule lists some methods to consider, but does not limit excavation within a tolerance zone to these methods. The rule also permits other mechanical methods or other technical methods that may

be developed to be used with the approval of the underground pipeline operator. When CoServ is excavating in the vicinity of its own pipelines, CoServ will be the entity deciding which method to use.

AGC of Texas expressed its belief that the language in §18.10(b) is not intended to require that the excavator secure the approval of the underground pipeline operator when using mechanical methods that represent current standard industry machinery or tools. AGC of Texas believes that §18.10 requires that an excavator exercise reasonable care within the tolerance zone. The language does include methods to consider, but is not intended to limit excavation within the tolerance zone exclusively to these methods.

The Commission agrees in part and disagrees in part with the comments of AGC of Texas. The Commission agrees that the standard set forth in §18.10 is that an excavator exercise reasonable care when excavating within a tolerance zone. The Commission disagrees, however, with AGC's comment that an excavator is not required to secure the approval of the operator when using mechanical methods that represent current industry machinery or tools. The rule is intended to require that an excavator secure the approval of the operator when using a mechanical method other than vacuum extraction or pneumatic hand tools. Other mechanical methods or other technical methods that may be developed may be used only with the approval of the operator.

CenterPoint recommended amending the first sentence of §18.10(b) so that it reads as follows: "When an excavation is to take place within the specified tolerance zone, an excavator shall exercise such reasonable care as may be necessary *to prevent damage to* (delete: for the protection of) any underground pipeline in or near the excavation area." In CenterPoint's view, this change clarifies that the purpose of the reasonable care that an excavator must exercise when excavating in the tolerance zone is to prevent damage to an underground pipeline. The suggested language also has the effect of incorporating the definition of "damage" in §18.2. The Commission agrees with CenterPoint's recommended change to §18.10(b) and has adopted the rule with this clarifying language.

TxDOT recommended deleting "with the approval of the underground pipeline operator," because the excavator should decide how to proceed. The Commission disagrees with this comment. The Commission is moving toward a more standardized use of the Best Practices, among which is increased and better communication among the various entities involved in an excavation project.

Air Products proposed adding a subsection (c) to §18.10 to read as follows: *"(c) The Operator may establish a larger tolerance zone commensurate with easement operator privileges."* The Commission disagrees with this recommendation regarding use of easements to define a tolerance zone. If an operator wishes to establish a tolerance zone larger than is prescribed in these new rules, that can be done with the agreement of the excavator, pursuant to §18.9.

PHMSA commented regarding §18.11 that data collection and analysis are essential to identifying trends in damage prevention and allocating resources in response to those trends. Accordingly, PHMSA expressly endorsed the reporting requirements set forth in §18.11. The Commission agrees with this comment.

With respect to §18.11(a), Air Products suggested limiting the damage reports to those incidents *"exceeding $5000 or violations of this rule resulting in near misses or dig rules"* caused by an excavator. The Commission disagrees with this suggested limitation on reporting; the Commission wants all reports so that staff will be able to evaluate the effectiveness of these rules and whether changes may be needed to improve pipeline safety.

Equistar commented that it did not find any value in both the operator and excavator having to submit formal reports to the Commission for the same incident. Equistar believes that the rule changes are meant to hold the excavators accountable for their performance. If this is true, then it would be better, and more efficient, to require the excavator to submit a report to both the Commission and the operator. Should the Commission see value in the report, it could require the operator to file a response, no later than ten days following receipt of an excavator's damage report to the Commission, with the operator's analysis of the incident. The Commission disagrees with Equistar; the Commission does find value in having the redundant reporting requirement. The Commission staff will review, evaluate, and reconcile the information to compile more comprehensive data about damage prevention.

TxOGA suggested making a clarifying addition to §18.11, relating to reporting requirements, to include the discovery of damage: "An operator shall submit the information to the Commission within 10 days of the incident *or the discovery of damage* through TDRF. . ." TxOGA encouraged the Commission to use penalty reviews and assessments in such a manner to encourage reporting all minor damage to pipelines as these events could ultimately lead to future catastrophic events. Pipeline operators want to have excavators accept and support the proposed damage prevention rule and related efforts by reporting all contact with a pipe without fear of punitive fines.

WTG also recommended that the Commission require only operators to report damages to their pipeline within ten days after discovering the damage. There will be situations where damage will occur to an operator's pipeline and it does not have actual knowledge of the incident at the time of the occurrence. If the excavator does not immediately report the damages to the pipeline operator, the pipeline operator will not be able to timely report to the Commission. A "discovery" concept is more realistic in the industry and prevents an operator from being exposed to potential violations and fines. WTG suggested modifying §18.11(a) to read as follows: "(a) Each operator of an underground pipeline shall report to the Commission all damages to its pipeline caused by an excavator. An operator shall submit the information to the Commission within ten (10) days of *obtaining actual knowledge of* the incident through TDRF, which may be accessed at webapps.rrc.state.tx.us using its assigned operator identification code."

CenterPoint also recommended changing the second sentence of §18.11(a) to recognize that an operator may not be immediately aware of damage to its facilities caused by an excavator, especially if the damage occurs only to a pipeline's coating or tracer wire. This change would require reporting when the operator has actual notice of the incident.

The Commission agrees with the comments of TxOGA, WTG, and CenterPoint on this issue, and in particular with efforts to adopt policies that encourage the ability for operators to take preventive action. As adopted, subsection (a) of the rule incorporates the "discovery" standard, as well as a correction to the URL published in the proposed rule. The correct URL for accessing the TDRF is http://www.rrc.state.tx.us/formpr/index.html.

CoServ commented regarding the requirement to report to the Commission all third-party damage within ten days via the Texas Damage Reporting Form. The preamble stated prior year data showing a minimum of 1,000 reports of pipeline damage and/or violations of safety rules. These appear to represent only the incidents required to be reported to the Commission (under 16 Tex. Admin. Code §8.210 and §8.301); the proposed regulations would require reports on *every* incident. Texas Excavation Safety System (TESS), one of three call centers in Texas, received more than 21,000 damage reports in 2006. Of that total, 3,600 were gas related, and 800 were unknown. CoServ concluded that under the proposed reporting rule, these numbers would increase dramatically.

More specifically, CoServ focused on the definition of "damage" in §18.2(1) as "including but not limited to defacing, scraping, displacement, penetration, destruction, or partial or complete severance of an underground pipeline or of any protective coating, housing, or other protective device of an underground pipeline; weakening of structural or lateral support of an underground pipeline that affects the integrity of the pipeline; or failure to properly replace the backfill surrounding an underground pipeline." CoServ commented that not all defacing and scraping affect the integrity of a pipeline. Manufacturers have a tolerance that allows the pipe to effectively operate. CoServ suggested adopting CGA's definition of damage as "any impact or exposure that results in the need to repair an underground facility due to a weakening or the partial or complete destruction of the facility, including, but not limited to, the protective coating, lateral support, cathodic protection or the housing for the line, device or facility." CoServ further asserted that "damage" such as failure to properly backfill, scraping, and defacing will be impossible to monitor and will increase operating costs without increasing safety. It would require a utility representative on site anytime an excavator is digging near gas facilities. This activity is reportable under the proposed rules, and utilities can be penalized under §18.11 for failure to report damage.

CoServ also noted that under the proposed rules, damage must be reported within ten days, but the rule does not specify the information required to be reported. Certain information, such as repair costs, are usually not available within ten days. Absent clarification, CoServ suggested a 30-day time line for reporting damage.

The Commission points out that TESS receives all damage reports, not just those for underground pipelines; the 1,000 reports that the Commission estimated it would receive were for reports of all damage incidents, not just those that are reportable under the current rules. In addition, the Commission anticipates proposing amendments to the current reporting rules in 16 Tex. Admin. Code §§8.210 and 8.301 to make them consistent with the new rules in Chapter 18 and with federal requirements. Further, the TDRF does not require reporting the damage amount, and each report can be amended for up to 30 days following submission. The Commission does want all reports of all damage to underground pipelines, which is the reason for the particular definition of "damage" included in these rules. The definition of "damage" in §18.2(1) is virtually identical to the definition of that term found in Texas Utilities Code, §251.002(4).

With respect to §18.11, Atmos requested the opportunity to provide comments on the damage reporting form once it is developed. Atmos noted, however, that complete information on an event, including all cost information, will rarely be available within ten days of an "incident," which is not a defined term in this rule. Also, if an operator is not advised of an event involving its pipeline, the operator will not be able to initiate, much less complete, a report within ten days. For example, if coating damage or improper backfilling by an excavator are reportable events, an operator will frequently not learn of the event until sometime in the future when operational issues arise. Therefore, Atmos submits that the proposed rule should be revised to provide that an operator will begin initial reporting efforts related to an event within ten days of learning of the event.

Additionally, several operators in the state have in place a policy that if an excavator damages a facility coating and the excavator advises the operator of that fact, that operator will repair the coating damage at no cost to the excavator. This safety practice encourages proactive notification instead of a potential undisclosed safety issue. Atmos submits that in such a circumstance, no report should be submitted. Likewise, no penalty action should be taken under §18.12 against an excavator who reports damage as required by proposed §18.11. Further, it is unclear whether actions by an operator that inadvertently impact its own facilities would require a report. Atmos would suggest that this issue rarely arises and that the Commission should not require reporting.

The Commission points out that damage amounts are not required on the new TDRF; the form matches the CGA's damage incident reporting tool ("DIRT"), on which cost information is not required. The Commission has already made clarifying changes in §18.11(a) to adopt a "discovery" standard for pipeline reporting of damage. The primary use of this information is to assist the Commission and the operators to develop better damage prevention techniques. The Commission commends Atmos for its policies that encourage excavators to promptly report damage to underground pipelines; however, failure to report is not necessarily going to result in enforcement actions or penalties. The Commission is aware that there are established working relationships between excavators and operators, and agrees that the first priority is repair of damaged pipelines.

Regarding new §18.11, TGA commented that because the operator is required to report all damages to its pipelines caused by an excavator through the TDRF system, the TDRF system should also include a means of reporting excavators caught excavating on a pipeline without notifying a notification center. This is addressed in Table 1, Line 3 as a specific line item, "failure to notify notification center" for penalty purposes. The Commission disagrees with this comment, because the TDRF is not primarily for enforcement of the Chapter 18 rules. TDRF is designed as a way to give the Commission more comprehensive data regarding damage to underground pipelines and better ways to prevent that damage. A violation such as a failure to notify a notification center should be called in as a complaint or reported through the safety e-mail at safety@rrc.state.tx.us.

Regarding §18.11(b), Marathon recommended inserting a requirement that an excavator call "9-1-1" before notifying the operator if the damage causes an imminent danger to life, property, or the environment. The Commission agrees that it is important to notify the pipeline of damage and has incorporated that requirement into new subsection (h) of §18.4 and amended wording in §18.11(b). The necessary emergency response actions, however, are not appropriately part of the new rules in Chapter 18. Presumably, excavators will have trained their employees on the proper steps to take in the event that a damage incident causes imminent danger to life, property, or the environment.

CenterPoint recommended amending §18.11(c) to read as follows: "Each excavator that begins excavating after it fails to receive a positive response to a second notice pursuant to §18.4(f) of this title, relating to Excavator Obligation to Avoid Damage to Underground Pipelines shall report that fact to the Commission through TDRF." This change is consistent with other of CenterPoint's suggested changes regarding the reporting and penalty provisions of the new rules. Also concerning §18.11(c), TxDOT recommended deleting "makes an additional call to the notification center pursuant to §18.4(e) of this title, relating to Excavator Obligation to Avoid Damage to Underground Pipelines, because the excavator . . . "

The Commission disagrees with the suggestion to limit reports of operator failure to respond to only the failure to respond to the second notice. The Commission wants reports of both failures of an operator to respond in order to capture more comprehensive data about the notification system and whether changes are necessary to improve pipeline safety and has adopted clarifying changes in both §18.5(c) and §18.11(c).

The Coalition suggested new text for §18.12, with proposed new §18.12 renumbered as §18.13. The new §18.12 would be entitled "Falsely Reporting an Emergency," and the text would read as follows: *"No person shall falsely report an emergency to a one call notification center, pipeline operator or locator in order to expedite the locating and/or marking of pipelines."* The Commission disagrees with this recommendation. After having reconsidered its proposal to penalize the false reporting of an emergency locate request. The Commission has determined that, ultimately, it is within the purview of the Texas One Call Board to determine and enforce standards for emergency locate requests. The false emergency locate requests are clearly a resource issue for operators, but not of the same magnitude, in terms of safety, as failure to locate, failure to make a positive response, or failure to give notice of intent to excavate. The Commission has removed the penalty proposed in Table 1, line 2.

By far, the greatest number of comments on the proposed new rules in Chapter 18 concerned new §18.12, the penalty guidelines. In general, operators expressed fear of being subject to exorbitant fines, as well as concern that the penalty provisions would create a disincentive to report pipeline damage incidents.

PHMSA's comments expressed strong support the Commission's proposal to adopt an enforcement system that requires all persons to comply with the rules, including State and local government entities that engage in excavation activities. The Commission's approach is consistent with CGA Best Practices and with the new civil penalty provisions of federal law, which apply to any person who engages in excavation activity.

PHMSA also commented that the fiscal note (including the additional personnel) appears realistic in view of the uncertainty associated with predicting the number of complaints and/or violations that will have to be investigated under the proposed rules. PHMSA noted that the recently adopted PIPES Act authorizes increased Federal funding of State pipeline safety programs, including a new grant program intended to encourage the development and enforcement of effective State programs for preventing construction-related damage.

In PHMSA's opinion, experience has taught that consistent imposition of civil penalties for failure to use one call systems is a key element of an effective damage prevention program. For that reason, PHMSA views the penalty guidelines set forth in proposed §18.12 as particularly commendable. While the amounts may be adjusted based on comments or experience, the overall concept of establishing guidelines but allowing the Commission the discretion to assess penalties based on the facts of each situation, has been proven effective in other States. PHMSA noted in particular the ability to impose penalties administratively (at the agency level) without the transaction costs and delays associated with the more traditional system of involving district attorneys and prosecutors. The Commission appreciates PHMSA's support of the rules as proposed and agrees with PHMSA's comments.

CenterPoint stated that the new rules would create a comprehensive regulatory scheme governing the process of notifying pipeline operators of intended excavations and insuring that those excavations are properly marked or the excavator is aware that no marking is required. They would first impose an obligation on excavators to utilize the Texas one call system to notify an operator of an intended excavation so it can positively respond to the notice as defined in the rules. However, CenterPoint commented, the rules correctly recognize that the excavator's responsibility to call does not end after its first call to a notification center. If an operator has not been able to positively respond within 48 hours, the excavator has an obligation to make a second call to the operator. The operator then must respond to this second call within four (4) hours. Only when the operator fails to respond to the second call may the excavator commence digging (see proposed new §18.3(e) and (f)).

CenterPoint commented that this regulatory scheme will have failed to achieve its goals in two instances: when an operator fails to respond to a second call and when damage to an underground pipeline occurs because of an excavation. CenterPoint believed that the reporting and enforcement mechanisms of the rule should focus on reducing these two risks. In order to accomplish this objective, CenterPoint suggested that excavators should be required to notify the Commission of the failure of an operator to positively response to a second notice rather than a first notice. This violation should carry the $2,500 fine presently assigned to a failure to respond to a first notice in item no. 11 of the penalty schedule. This would not prevent the Commission from penalizing the failure to respond to first notices, but would help the Commission concentrate its resources on those violations that clearly create the most immediate danger to underground pipelines. It would also reduce duplicative reporting to the Commission. Under the current reporting mechanism, the Commission could receive as many as four reports for every instance of damage, thus multiplying its administrative burden.

The Commission reiterates that it wants reports of all failures to comply, including failures to provide a positive response to both a first notice and a second notice, and has made clarifying changes in the adopted rules as explained in previous paragraphs.

WTG commented that while the language of §18.12(a) is good, it is concerned that this subsection concedes the fact that some fine will be accessed in all situations. WTG is concerned that the amount of fines, while enhancing the coffers of the State of Texas general fund and ultimately benefitting the Commission's through its budget process may be sending the wrong signal to excavators and pipeline operators. A new rule takes time to be understood and followed. The assessment of fines immediately will encourage non-reporting and non-compliance. WTG recommended that no fines be assessed for the first year to give everyone a reasonable opportunity to be in compliance. In the alternative, WTG favored a permitting process for excavators in-

stead of assessing fines. WTG also liked eliminating the word "penalty" altogether and substituting "fee" throughout the rule. In WTG's view, the rule as written has a criminal aspect to it that is unwarranted. If the State of Texas needs money, WTG commented that it should be called a fee and not make everyone out to be criminals.

The Commission disagrees with WTG's assertion that a fine will be assessed for every violation. Subsection (e) clearly states that depending upon the nature of and the consequences resulting from a violation of this chapter, the Commission may impose a non-monetary penalty, such as requiring attendance at a safety training course, or may issue a warning. Further, the Commission has discretion to impose a penalty, monetary or otherwise, or not. The goal of the Commission is not to enhance the coffers of the State and benefit the Commission in its budget process; the very nature of penalties means that they are an uncertain method of financing any on-going program. If the Commission achieves its goal of increasing compliance every year, there will be few or no fines assessed, certainly not in amounts sufficient to fund the safety programs. The Commission agrees that sometimes a new rule takes time to be understood and followed, but the Commission disagrees that it will take time for these new rules to be understood and followed, because excavators and pipelines have been required to use the One Call system since 1999. The Commission disagrees with WTG's recommendation that no fines be assessed for the first year to give everyone a reasonable opportunity to be in compliance, because the Texas One Call system has been in place for nearly ten years and because the statutory authority under which the new rules in Chapter 18 are being adopted became effective nearly two years ago. The Commission disagrees with WTG's suggestion that there be a permitting process for excavators instead of assessing fines, because the Commission does not have statutory authority to issue permits to excavators. Further, the issuance of a permit is no guarantee that the permit holder will comply with the rules, just as the penalty system does not offer any such guarantee. The Commission disagrees with WTG's suggestion the word "penalty" be replaced with the word "fee" because the Commission has authority under Texas Natural Resources Code, §81.0531, and Texas Utilities Code, §121.206, to assess a civil penalty for violations of statutes and rules pertaining to safety, not to impose a fee. The Commission disagrees that the rule "makes everyone out to be a criminal." The penalties are civil, not criminal. The Commission intends to focus its efforts on compliance but recognizes that there is some deterrent effect to being able to impose monetary penalties for violations.

SM&P commented that due to the number of locate tickets for which operators will be required to respond, the penalties proposed by the Commission are punitive in nature and will risk compromising the integrity of the utility locate system. In 2006 TESS received 1,891,277 locate requests resulting in 9,498,579 locate tickets. SM&P believed that the suggested rules and the fines associated with them will have an undesirable destabilizing effect on the safety and effectiveness of utility locating. In SM&P's view, the Commission's proposed definition of persons would be unduly burdensome to larger operators and locating companies who would have a disproportionate amount of tickets compared to others over the course of a year. SM&P believed that the fines listed in the Penalty Calculation Worksheet should be removed from the proposed rule changes. In the alternative SM&P believed it would be better to suspend the fines and their enhancements for two years after the rules take effect to allow time for all stakeholders to educate, train and develop effective processes as needed.

The Commission agrees that the penalty amounts are punitive; that is their purpose. The Commission disagrees that monetary penalties risk compromising the integrity of the utility locate system or will have a destabilizing effect on the safety and effectiveness of utility locating. The Commission recognizes that an entity that works a large number of locate tickets would have a higher likelihood of violating a rule and potentially being subject to a penalty. However, an entity of any size could violate the rules in a way that results in injury or death. Further, in §18.12(b)(6), the Commission has added as factors the Commission may consider the number of locate requests received and responded to by an operator and the number of location notifications given by an excavator in the previous year.

Texas Natural Resources Code, §81.0531, and Texas Utilities Code, §121.206, require the Commission by rule to adopt guidelines to be used in determining the amount of the penalty for a violation that relates to pipeline safety. The guidelines are required to include a penalty calculation worksheet that specifies the typical penalty for certain violations, circumstances justifying enhancement of a penalty and the amount of the enhancement, and circumstances justifying a reduction in a penalty and the amount of the reduction. By statute, the guidelines must take into account the permittee's history of previous violations, including the number of previous violations; the seriousness of the violation and of any pollution resulting from the violation; any hazard to the health or safety of the public; the degree of culpability; the demonstrated good faith of the person charged; and any other factor the Commission considers relevant.

Finally, the Commission points out that the State of Texas leads the nation in the number of hits per miles of pipeline. The standard federal penalties are much higher--on the order of $25,000 per violation, up to $100,000 per day. The Commission expects that the penalty provision will focus the attention of those who are required to comply with the rules, and declines to remove the penalty provision from the rules.

CoServ commented that CGA recently revealed that the overwhelming majority of accidents are the result of unsafe practices by excavators, but that under proposed new §18.12, the suggested penalties would hit utilities harder. Utilities must respond to a far greater number of locate ticket requests than excavators. In 2006, TESS received 1,891,277 locate requests resulting in 9,498,579 locate tickets. According to TESS, the top excavator who called for locates made 69,514 requests in 2006. CoServ recommended that the Commission take the following actions:

1. Suspend the penalty enhancements for the first two years the rules are in effect. This would provide all stakeholders an education and training period so that appropriate and reliable processes can be developed, implemented, tested and, as necessary, refined.

2. Make the penalty enhancements proportional to the number of locate requests. Gas utilities receive locate tickets from hundreds of different excavators, which results in a far greater number of locate tickets than notifications issued by an individual excavator. As written, the enhancement provision would result in far greater fines against operators, when the evidence clearly shows that third-party excavators are the principal cause of damage. Enhancements of the penalties could be based upon a percentage or some other means that would recognize the enormous disparity in ticket volumes.

3. Ensure that the rules follow CGA Best Practices, which suggest ideal characteristics for enforcement authorities to ensure that all claims of damages are investigated without bias or the perception of bias. It also suggests that stakeholders be involved in periodic reviews of the damage prevention program.

4. Provide for an appeals mechanism in the penalty provisions, such as those in place in Virginia. The state has an advisory committee, made up of stakeholders, that has partnered with its state utility regulatory agency. The advisory committee hears cases sent by the state authority after it investigates the claims. The advisory committee sees the evidence and listens to testimony by all parties involved and renders a decision. CGA discusses this program in its Best Practices.

5. Restructure the proposed penalty structure to allow a utility to work with responsible excavators who call for locates and who report damage when it occurs. Many contractors are unlikely to report damage if they know they will be fined. Instead of reporting all incidents directly to Commission, the following reporting structure should be adopted:

a. Excavators must report all "damage"--as defined by CGA--to the utility or a call center. If reported to a call center, the call center notifies the utility.

b. Utilities must report all damage as required by 49 CFR Part 191 to the Commission; utilities should have discretion about whether to report damage that does not fall under this requirement.

c. Excavators will not be fined if they damage a line while following the rules and report the damage to the utility or a call center.

d. The most dangerous situation involves an excavator who cuts a line and does not report the damage or covers up the damage. CoServ suggested a $5,000 fine for excavators that fail to report damage described in "a" above.

6. Drop the "Failure to comply with Chapter 18" penalty. Excavators and utilities will be penalized in other ways due to the proposed system. There is no need for this penalty under the proposed rules.

7. Make the fines for failure to make a positive response ($2,500) and failure to notify a call center of plans to excavate ($1,000) the same amount.

The Commission disagrees with CoServ's recommendation to suspend the penalty enhancements for the first two years the rules are in effect. The Commission points out that the One Call program has been in place since 1999, which means that excavators and operators have had nearly ten years to become educated on the need to locate underground facilities before excavating and the procedures for giving notice through the notification centers. The Commission disagrees with suggestions that would have the effect of further delaying implementation of appropriate and reliable pipeline safety procedures that have been in place in other states.

The Commission disagrees that penalty enhancements necessarily should be proportional to the number of locate requests. Just because gas utilities receive locate tickets from hundreds of different excavators which may result in a far greater number of locate tickets than notifications issued by an individual excavator doesn't mean that rates of compliance will be lower. The Commission recognizes that an entity that works a large number of locate tickets would have a higher likelihood of violating a rule and potentially being subject to a penalty. However, an entity of any size could violate the rules in a way that results in injury or death. In §18.12(b)(6), the Commission has added as factors the Commission may consider the number of locate requests received and responded to by an operator and the number of location notifications given by an excavator in the previous year.

The Commission disagrees that as written, the enhancement provision would necessarily result in far greater fines against operators. The Commission also disagrees that enhancements of the penalties necessarily should be based upon a percentage or some other means that would recognize the enormous disparity in ticket volumes. The Commission has discretion to impose a non-monetary penalty, such as requiring attendance at a safety training course, or to issue a warning. Further, the Commission has full discretion to impose a penalty, monetary or otherwise, or not.

The Commission disagrees with CoServ's recommendation that the rules should follow CGA Best Practices regarding ideal characteristics for enforcement authorities to ensure that all claims of damages are investigated without bias or the perception of bias, because it is unnecessary. The Commission already has in place procedures and practices for investigating incidents and accidents, and for bringing enforcement actions, if necessary. There is also no barrier to stakeholders offering their views regarding the damage prevention program, and no prohibition on any interested person filing a petition for rulemaking to change the rules.

The Commission disagrees with CoServ's comment that the penalty provisions should also provide an appeals mechanism, because it is unnecessary. The penalty provisions in new §18.12 apply in enforcement proceedings, in which the due process standards of the Administrative Procedure Act and the Commission's rules apply. There is no statutory authority under which the Commission could delegate to an industry advisory committee the authority to preside over enforcement cases.

The Commission disagrees that the proposed penalty structure does not allow a utility to work with responsible excavators who call for locates and who report damage when it occurs. The Commission specifically disagrees with the premise of CoServ's comments that fines will always be imposed. As stated in previous paragraphs, the Commission has discretion to impose a penalty, monetary or otherwise, or not, or to take into account the listed factors in determining the amount of any monetary penalty.

The Commission disagrees in part with CoServ's recommendation that excavators must report all "damage," as defined by CGA, to the utility or a call center. If reported to a call center, the call center notifies the utility. The Commission adopts new §18.4(h) and 18.11(b) with clarifying language that specifies reporting of pipeline damage to the operator through the notification centers. The Commission defines "damage" in new §18.2(1). The Commission also disagrees with CoServ's recommendation that utilities must report all damage as required by 49 CFR Part 191 to the Commission, and that utilities should have discretion about whether to report damage that does not fall under this requirement, because the requirements of Chapter 18 apply to more pipelines than only utilities. Further, the Commission wants reports of all pipeline damage in order to compile comprehensive data regarding damage incidents and the effectiveness of the Commission's new rules in Chapter 18.

The Commission disagrees with CoServ's suggestion that excavators not be fined if they damage a line while following the rules and report the damage to the utility or a call center; however, the

Commission points out that such an event might or might not be the subject of an enforcement action, and that even if it is, the fact that the excavator followed the rules and reported the damage would be considered under "demonstrated good faith," and there might not be a monetary penalty associated with it.

In response to and agreement with other comments, the Commission has made all recommended penalty amounts $1,000. The Commission agrees that it is important not to create disincentives to excavator reporting of pipeline damage.

The Commission disagrees with CoServ's suggestion to drop the "failure to comply with Chapter 18" penalty. This provision is a restatement of the Commission's authority to bring an enforcement action for any violation of the Chapter 18 rules, not just the specific conduct listed in Table 1.

TxDOT commented with respect to §18.12(a) that it is not clear that fines can be assessed in the manner described. The Commission disagrees with the comment. Texas Natural Resources Code, §81.0531, and Texas Utilities Code, §121.206, require the Commission to adopt by rule guidelines to be used in determining the amount of the penalty for a violation that relates to pipeline safety. The guidelines are required to include a penalty calculation worksheet that specifies the typical penalty for certain violations, circumstances justifying enhancement of a penalty and the amount of the enhancement, and circumstances justifying a reduction in a penalty and the amount of the reduction. The guidelines must take into account the permittee's history of previous violations, including the number of previous violations; the seriousness of the violation and of any pollution resulting from the violation; any hazard to the health or safety of the public; the degree of culpability; the demonstrated good faith of the person charged; and any other factor the Commission considers relevant.

Devon Energy commented that the goal of Chapter 18 is to protect the public by reducing damage to underground pipelines. The proposed rule includes a series of penalties for violations of Chapter 18 as a means of reaching this goal. Devon agreed that operators and excavators who do not comply with Chapter 18 should be subject to financial penalties.

Devon's first concern was that the penalties, as presently structured, may be a disincentive to report damage to underground pipelines. Devon noted that there is a proposed penalty for "failure to report damage by third-party," however, there is no specific penalty for an excavator failing to report damage. Item 1 in Table 1 (failure to comply with Chapter 18) is generic enough to cover any violation of Chapter 18, but in Devon's view, excavator self-reporting is important enough to warrant a listed violation. No operator can monitor all of its underground facilities 100 percent of the time. Operators, must to some extent, depend on excavators to report damage. When an operator knows about damage, the operator will repair it and prevent any further threat to public safety. Unreported damage can become a threat to the public months or years after the initial incident. Devon recommended that excavators be required to report damage to a pipeline immediately to Texas One Call. "Immediately" should be interpreted as two hours or less. Texas One Call would then treat the call as it does emergency locate requests. Operators would have up to 4 hours to respond to the "damage" ticket. Furthermore, Devon suggested, the excavator should not be permitted to cover the exposed pipeline without approval of the operator.

Devon recommended that failure to report damage to a pipeline be subject to a penalty. Because failure to report could create a threat to the public at some unknown time in the future and because it undermines the entire damage prevention process, in Devon's view it should be subject to severe penalties. It could be argued that determining if someone did not self-report may be difficult. However, Devon maintained that failure to report is too important to be ignored, and that Chapter 18 allows any third-party to make reports, which should encourage self-reporting.

Devon further commented that penalties need to be carefully structured to enhance the goal of Chapter 18. The question should be asked: "besides failure to self report, what violations pose the greatest potential threat to public safety?" Two tiers of violations should be developed. Tier I violations would represent those behaviors that have the greatest potential impact on public safety. Tier II violations would include those that involve a failure to comply with Chapter 18 but have less potential impact on public safety. The Tiered Violation approach provides other opportunities to promote damage prevention. First, the penalties should be weighted so that Tier I violations would incur the largest fines. Tier II penalties would be less punitive and aimed more at educating excavators and operators on successful damage prevention techniques, for example, the proper use of white-lining.

Devon continued that the failure of an excavator to report damage immediately to Texas One Call should be a Tier I violation, because the operator needs to know about the damage so that it can effect repairs. The failure of an excavator to report damage via the Texas Damage Prevention Form does not pose a potential threat to the public, so it should be a Tier II violation.

In Devon's proposal, Tier II Violations could be structured so an excavator or operator who improves its damage prevention program will be given "credit" for its efforts. To measure improvement, Devon suggested calculating a compliance rate on the most recent complete calendar year. Devon's position is that rates of compliance, rather than a simple count of violations, are needed to fairly reflect an excavator's or operator's efforts for improvement. Some excavators and operators handle hundreds of One Call locates or locate requests per day while others may be involved in only a few dozen each calendar year.

Devon found the proposed structure of recommended penalties to be biased against excavators and operators that handle large volumes of One Call tickets. As an example, Devon posited two operators, *A* and *B*, who both had 50 identical violations in a calendar year. Operator *A* handles 100,000 locate requests per year for a compliance rate of 99.95 percent, but Operator *B* handles 1000 locate requests per year for a compliance rate of 95 percent. Clearly Operator *A* has a better damage prevention program than Operator *B* but each would be subjected to the same penalties. Item 25 of Table 1 does provide for a "reduction for demonstrated good faith of person charged" but by using compliance rates, Devon argued, "good faith" could be quantified.

For the Tier II compliance rates to work, Devon commented, violations must have a specified life span. As proposed, Chapter 18 does not specify how long a violation can effect the penalty enhancements in Table 1. Devon suggested a one-year life span for Tier II violations and a three-year life span for Tier I violations, because of their potential to impact public safety. Tier I violations could be calculated into the compliance rate but they would have to be weighed to reflect their severity over Tier II violations. Devon concluded that it would be simpler to omit them from the compliance rate calculation at this time and calculate rates only for excavators with Tier II violations.

Devon's comments continued that besides quantifying "good faith," the Tier II scheme affords an opportunity to set goals for improvement to Texas' damage prevention efforts. A compliance percentage could be determined as needed for an operator or excavator by the following formula:

*Rate = (1 - (number of Chapter 18 violations)/(number of ticket requests made and/or tickets received))*100*

The Commission could then establish goals in coming years to improve the rate by a specified amount. Excavators and operators who meet the goals would be eligible for penalty reductions.

At this point, Devon conceded, there are insufficient data to determine existing compliance rates. If this rule is implemented in September of 2007, Devon suggested that all operators and excavators be assumed to a have compliance rates that meet the Commission's goal for the remainder of 2007. Data collected during that period could be used to determine a rate for 2007 that would be used to set goals for 2008. In the penalty structure as proposed, Operators *A* and *B* would be subject to penalty enhancements of five times the penalty amount because they each had more than 10 violations. In Devon's proposal, all operators and excavators are assumed to be in compliance with the established damage prevention goals for the remainder of 2007 and would be eligible for penalty reductions.

Devon suggested that this time period could be used to educate all affected parties on how this rule will work. In particular, excavators and operators could be shown that when they meet Commission compliance goals their penalties are reduced by "x" amount. Also it would be made clear that there are no reductions for Tier I violations.

Devon made additional suggestions with respect to the proposed penalty provisions. Devon recommended that all penalty amounts for violations listed on lines 1 through 16 of the table be $500. These would be the Tier II violations. Enhancements would be Tier I violations, and would carry monetary penalties of $5000 to $25000.

Devon also commented that the recommended penalties shown on Proposed Table 1 showed that the penalty for "pipeline operator did not provide positive response" was higher than other penalties, while the penalty for "excavator failed to protect locate markings" was lower than other penalties. Devon saw no justification for these differences. Devon recommended a penalty amount of $500 rather than $1000 because the reason for Tier II penalties is more educational than punitive.

Devon suggested a qualifying condition, "other than listed conduct," to the penalty listed on line 1, so that it would not cause an additional penalty to be added to every incident.

Devon recommended a reduction of 25-75 percent for meeting the compliance rate as Line 18. The range of 25-75 percent allows for the reduction to reflect by how much an operator or excavator exceeds the compliance rate goal for a year.

Devon commented that an increase in the penalty amount, in the range of 25-250 percent, be calculated for exceeding the compliance rate and included on Line 20, as a substitute for the penalty enhancements. Devon contended that this range is sufficient to encourage excavators and operators to develop more effective damage prevention programs. Additionally, this reserves larger fines for the more serious Tier I Conduct.

Devon would substitute "Tier I Conduct" for penalty enhancements. Devon would add two violations from the proposed Table 1--"Impact to a residential or public area" and "Reckless conduct of person charged"--to Devon's proposed excavator failure to self-report to Texas One Call. The proposed three-year life span would allow recent history of Tier I penalties to determine if a fine is in the low or high end of the $5,000 to $25,000 range. Devon suggested that a longer life span for Tier I penalties could interfere with incentives to promote continual improvement of damage prevention programs, thus Devon would reduce penalties for what are now labeled Tier II conduct to $500.

Devon recommended that the original suggested penalty for Item 16 be changed from "failure to report damage by third-party" to "failure to report damage to the TDRF." This will include third-party damage and provide a smaller penalty for a failure to report to the TDRF than to the Texas One Call. Devon would also move "reduction for settlement before hearing" lower on the table in order to include penalties associated with both Tier I and Tier II violations.

The Commission agrees that excavators failing to report damage is significant. Line 16 on Table 1 reads "failure to report damage by third party," which the Commission recognizes could be ambiguous. The Commission has changed this to distinguish between excavator and pipeline duties to report damage to underground pipelines.

The Commission agrees that unreported damage can become a threat to the public months or years after the initial incident. The Commission agrees also that an excavator should report pipeline damage directly to a notification center, within two hours or less, which would then treat the call as an emergency line locate request. Operators would have up to four hours to respond to the "damage" ticket. Furthermore, Devon suggested, the excavator should not be permitted to cover the exposed pipeline without approval of the operator. Section 18.11(b) has been adopted with amended language consistent with this recommendation. The Commission has made a conforming change in the adopted versions of §18.4, by adding subsection (h) requiring an excavator to notify an operator of damage to a pipeline through a notification center, and of §18.5, by adding a new subsection (d) that requires an operator receiving notice of damage to an underground pipeline to respond within four hours.

The Commission neither agrees nor disagrees with Devon's suggestions regarding the structure of penalties. The Commission recognizes the value in establishing a risk-based approach to penalties, and in having some objective means of evaluating "good faith." However, the Commission does not envision the penalty provisions as the centerpiece of the rules in Chapter 18. The Commission will be reviewing and analyzing the data reported through the TDRF system to determine whether the Chapter 18 standards have been clearly stated and effectively communicated. For now, the Commission will use the penalty matrix substantially as proposed; this is nearly identical to the penalty matrix adopted in 16 Tex. Admin. Code §8.245 (relating to Penalty Guidelines for Pipeline Safety Violations) for natural gas pipelines, and it has worked well.

Texas Gas expressed concern that §18.12 and the accompanying penalty guidelines set out in Table 1 disproportionately impact operators. As an initial matter, while the penalty guidelines recommend $1,000 for most infractions, the guidelines recommend $2,500 for "failure to provide positive response." By its nature, this infraction only applies to an operator that has the obligation to provide a positive response to a line locate request. The rule provides no justification why this particular infraction should merit a fine 150 percent higher than other infractions. For instance,

infractions that are specific to excavators, such as "failure to notify notification center" or "failure to include method for positive response," merit only a $1,000 fine under the guidelines, even though notifying a notification center and providing a method for responding are necessary preconditions to an operator providing a positive response. Moreover, the guidelines recommend only $1,000 for falsely reporting an emergency line locate request, even though this infraction goes to fraudulent behavior and not mere negligence. Texas Gas suggested that the suggested penalty for "failure to provide positive response" should be $1,000, consistent with the suggested penalties for the other infractions listed on Table 1.

Texas Gas noted that the only other infraction listed on Table 1 that does not have a suggested penalty of $1,000 is for a failure to protect locate markings, which has a suggested penalty of $500. Since the ultimate aim of the rules is to locate and mark underground pipelines before excavation, Texas Gas is unclear why conduct which may negate the entire focus of the rules by failing to maintain locate markings before excavation is of apparent diminished importance to the Commission.

The Commission has agreed with other comments recommending that the penalty for failure to provide a positive response should be reduced to $1,000, and agrees that the penalty for failure to protect line markings should also be set at $1,000. The Commission points out, however, that the primary reason for proposing a $2,500 penalty for failure to provide a positive response was that there were so many instances of this occurring. The Commission further points out that the penalty amounts shown in the table are only guidelines to be considered in determining the amount of administrative penalties for violations of the requirements of Chapter 18. The guidelines in no way limit the Commission's authority and discretion to assess administrative penalties in any amount up to the statutory maximum when warranted by the facts in any case. The amount of any penalty requested, recommended, or finally assessed in an enforcement action will be determined on an individual case-by-case basis for each violation, taking into consideration the factors set out in §18.12(b).

TPA addressed several areas of the fines and penalties section of the proposed rule including the parity of fines, the schedule of fines, and fining individuals for reporting false emergencies. In reviewing the proposed rule, and specifically the fines and penalties section, TPA noted that the proposed fine for failing to make a positive response was significantly higher than any other proposed fine. TPA requested that the suggested fine be adjusted to be in alignment with the all other suggested penalties. TPA suggested that all penalties be equal until greater data are collected and justification made to increase or decrease the recommended fines according to the activities that result in the greatest known risk or activity that endangers the safety of the public or workers and the integrity of the pipeline itself.

Further, TPA expressed concern over the manner in which fines and penalties will increase as the number of violation occurs. Larger pipeline companies can receive tens of thousands, and even hundreds of thousands, of locate requests each year. Under the proposed rule, a pipeline company could receive millions of dollars in fines even if it had a 99.99 percent accuracy with regard to the number of potential excavations near buried pipeline facilities successfully responded to during the course of a year. While a larger excavation firm may only have to several dozen calls per year, the potential damage to a pipeline facility is far greater for those each of those calls. And yet, the potential fines for the failure to follow the proposed rule are substantially less than that of the pipeline operator. TPA respectfully requested that the Commission provide an alternative penalty structure for operators, and, specifically, an alternative structure for penalty enhancements for operators, when the rule is considered for final adoption.

Last, TPA requested that the Commission address the penalty provision for anyone who falsely reports an emergency. One of the greatest issues pipeline operators face is responding to false emergencies that are actually made in order to accelerate a pipeline operators response to a locate request. While a provision in the penalty section covers falsely reporting an emergency, the proposed rule does not specifically prohibit such actions by an excavator. TPA is concerned that there is no specific violation that can be cited in order to penalize an excavator for such actions.

The Commission disagrees with the recommendation to have a separate penalty structure for operators. The Commission agrees that, at least initially, all recommended base penalty amounts will be $1,000. The Commission does not anticipate that fines will be in the "millions of dollars," unless these problems are far more widespread than has been documented. The Commission views the reporting requirements as far more valuable in terms of analyzing how well the new rules in Chapter 18 are working. The Commission has also added "number of locate calls received" and "number of locate notices given" as factors to be considered in determining enhancements or mitigation of recommended penalties. Finally, the Commission has reconsidered its proposal to penalize the false reporting of an emergency locate request. The Commission has determined that, ultimately, it is within the purview of the Texas One Call Board to determine and enforce standards for emergency locate requests. The false emergency locate requests are clearly a resource issue for operators, but not of the same magnitude, in terms of safety, as failure to locate, failure to make a positive response, or failure to give notice of intent to excavate. The Commission has removed the penalty proposed in Table 1, line 2.

The Coalition also requested that the Commission address four issues relating to the fines and penalties section of the rulemaking. The issues relate to the parity of violations, falsely reporting an emergency, the penalty schedule for multiple violations, and fining excavators for failing to report certain types of violations.

The first issue relates to the recommended fine attributable to the failure to provide a positive response under §18.5. While the Coalition agreed that any operator failing to provide a positive response would not be in compliance with the provisions of this rulemaking, the Coalition questioned the amount of the recommended penalty of $2,500 in the proposed rule. There are many other violations listed on the "Suggested Penalties" table; however, no other violation is associated with the same level of monetary penalty as that for positive response. The Coalition questioned the parity of positive response and that of several other violations including the failure to notify a notification center and the failure to wait the required time before digging. The Coalition respectfully requested that this parity be addressed. This can be accomplished by either adjusting the fine for similar violations to the same level cited for positive response, or reducing the recommended fine for positive response to the level of similar violations.

The Coalition also sought additional clarification from the Commission with regard to violations relating to falsely reporting an

emergency to a pipeline operator. The definition of "emergency" is established in the definition section of the proposal. And line 2 of the "Suggested Penalties" worksheet states that falsely reporting an emergency line locate request is indeed a violation. However, there is no provision found within the rule that actually prohibits an excavator or other party from falsely reporting an emergency in order to expedite the marking of facilities by an operator. The reporting of emergency situations is a huge problem for underground facility owners. False emergencies take substantial time and resources away from marking those facilities that have been correctly requested by excavators as part of the one call notification process. The Coalition requested that a provision be added to specifically address falsely reporting an emergency for clarification and enforcement purposes.

The Coalition also requested that the final rule be adjusted to address concerns with the manner in which fees and penalties are escalated when violations occur. While the Coalition supports increasing the fees for violations outlined in §18.12(b), the Coalition believes the penalties for repeat violations have the potential to be unfair to operators who receive significantly higher volumes of locate requests and/or significant miles of pipeline. For example, some pipeline operators process hundreds of thousands of tickets per year; while some large-scale excavators may only request several hundred locates per year. The higher volume pipeline operators potentially will be subject to substantially higher absolute levels of fines due to the penalty amounts being multiplied if even two incidents occur. While pipeline operators strive to ensure a perfect record, violations will occur. The Coalition requested that some alternative manner or schedule be evaluated and established for fining those with higher volumes of locate tickets or requests.

Last, the Coalition does not believe that an excavator should face fines and penalties for failing to report damage to an underground pipeline, suggesting that this would create a disincentives for any stakeholder, in particular the excavators, from being an active part of the process.

The Commission agrees that, at least initially, all recommended base penalty amounts will be $1,000. The Commission points out, however, that the penalty amounts shown in the table are only guidelines to be considered in determining the amount of administrative penalties for violations of the requirements of Chapter 18. The guidelines in no way limit the Commission's authority and discretion to assess administrative penalties in any amount up to the statutory maximum when warranted by the facts in any case. The amount of any penalty requested, recommended, or finally assessed in an enforcement action will be determined on an individual case-by-case basis for each violation, taking into consideration the factors set out in §18.12(b). The Commission has also added "number of locate calls received" and "number of locate notices given" as factors to be considered in determining enhancements or mitigation of recommended penalties. The Commission has reconsidered its proposal to penalize the false reporting of an emergency locate request. The Commission has determined that, ultimately, it is within the purview of the Texas One Call Board to determine and enforce standards for emergency locate requests. The false emergency locate requests are clearly a resource issue for operators, but not of the same magnitude, in terms of safety, as failure to locate, failure to make a positive response, or failure to give notice of intent to excavate. The Commission has removed the penalty proposed in Table 1, line 2.

The Commission disagrees with the premise of the Coalition's recommendation that an excavator not face fines and penalties for failing to report damage to an underground pipeline, because nothing in new §18.12 requires that a monetary penalty be imposed for any violation. To the contrary, the rule expressly provides that the Commission may impose a non-monetary penalty, such as requiring attendance at a safety training course, or may issue a warning, depending upon the nature of and the consequences resulting from the violation. The Commission recognizes that having penalty provisions does not guarantee compliance with the rules, but also recognizes that there is some deterrent effect to being able to impose monetary penalties for violations.

CenterPoint commented that while the penalty scheme in proposed §18.12 appears to be based on the Penalty Guidelines for Pipeline Safety Violations contained in 16 TAC §8.245, the enhancement of penalties based on repeat violations would have the effect of unfairly penalizing CenterPoint and other large local distribution companies that handle hundreds of thousands of locates annually. In addition, the range of the enhancement based on impact to a residential or public area is significantly higher than the $1,000 - $15,000 level established in §8.245. CenterPoint thus also supports the comments of Atmos, Texas Gas Services, and the Texas Pipeline Association regarding the penalty structure and urges the Commission to reexamine it in light of these comments. The Commission has considered all the comments regarding the penalty structure, and, in response, has made some clarifying changes in the adopted rules.

WTG commented that §18.12(b)(1) is too broad. First, WTG questioned which violation will be considered under this part. WTG asked whether the Commission is talking about only violations of this rule or whether violations of any other laws, regulations, or rules would be taken into consideration. WTG inferred that the Commission intends to consider only previous violations of Chapter 18 and not anything else, and so WTG recommended that subsection (b)(1) be restricted only to violations of Chapter 18 rules.

Second, WTG noted that there is no time limit on previous violations. WTG recommended that a time limit be established so that any violation that occurred more than four years will not be considered.

Third, WTG asked whether the rule would ever be interpreted to make a current owner of pipeline properties responsible for the actions of previous owners. WTG asked, for example, whether it would be responsible for higher penalties and enhancements because of a previous owner's violations on a pipeline that WTG might acquire. WTG inferred that the Commission does not intend this type of consequence, and therefore recommended that some guidance be given in the rule to eliminate this possibility.

The Commission agrees with the recommendation to use only prior violations of Chapter 18 rules in calculating any penalty enhancements under new §18.12; that has always been the intent. However, the Commission disagrees with limiting prior violations to those within the prior four years. The Commission will consider all prior violations, but the time period over which those have occurred would also be taken into account. For example, an entity that had two prior violations in the past five years would be viewed differently from an entity that had two prior violations in the past six months. Finally, the Commission agrees that a current owner is not responsible for the conduct of a prior owner. The Commission declines to make any changes in the text of

the adopted rule, however, because the rule is already written to apply to the conduct of "the person charged."

With respect to §18.12(b)(2), API and AOPL commented on the factors set out that are used to determine recommended penalty amounts. API and AOPL commented that the threshold for consideration should be revised so that even damage to a pipeline (or other underground appurtenance) is considered in the penalty equation. For the rule to speak in terms of pollution resulting from a violation is to imply that a release incident has occurred, which most likely would be in the case of a pipeline transporting hazardous liquids. Yet damage to a gas or liquid pipeline very well may result in significant costs for examination and repairs when reported to the pipeline operator, or may create a condition conducive to long-term deleterious effects to the pipeline if not reported. A mere scrape to pipeline coatings may initiate damaging corrosion on a steel pipeline. API and AOPL urged that the penalty consideration factor must prompt consideration of damage to a pipeline to a degree less than damage that causes a release and thus pollution. API and AOPL believe that the rule may then result in a greater deterrent effect upon those who might otherwise be inclined to take their economic and safety chances while excavating. API and AOPL encouraged the Commission to revise this rule to include damage to a pipeline as a penalty consideration factor in §18.12(b)(2).

The Commission recognizes that not every pipeline damage incident will cause a spill or release resulting in pollution, but certainly some will. That is just one factor among others that the Commission, by statute, must consider. The Commission must weigh whether the requirement to report all damage (and the resulting penalty for failure to do so) may create a disincentive for excavators to report damage to the operator and to the Commission. For the present, however, the Commission finds that §18.12, as adopted, will provide fair notice of the recommended penalties that could be sought in an enforcement proceeding.

WTG also commented that in §18.12(b)(2), "seriousness" is too subjective to be used as a standard, and suggested that the Commission substitute "amount of damage to the pipeline" instead. In WTG's opinion, this would be more objective and allow for better assessment of penalties or fees.

The Commission disagrees with this comment. Texas Natural Resources Code, §81.0531, and Texas Utilities Code, §121.206, require the Commission by rule to adopt guidelines to be used in determining the amount of the penalty for a violation of a provision of Title 3 of the Natural Resources Code, or a rule, order, license, permit, or certificate that relates to pipeline safety. The guidelines must include a penalty calculation worksheet that specifies the typical penalty for certain violations, circumstances justifying enhancement of a penalty and the amount of the enhancement, and circumstances justifying a reduction in a penalty and the amount of the reduction. By statute, the guidelines must also take into account: (1) the permittee's history of previous violations, including the number of previous violations; (2) the seriousness of the violation and of any pollution resulting from the violation; (3) any hazard to the health or safety of the public; (4) the degree of culpability; (5) the demonstrated good faith of the person charged; and (6) any other factor the Commission considers relevant. Because "seriousness of the violation" is a statutory standard, the Commission has determined that it is appropriate to be included in the rule. Certainly the amount of damage to a pipeline would be one measure of "seriousness," as would the amount of damage to other property, and whether there is any personal injury and/or loss of life.

In §18.12(b)(4), WTG objected to the use of "degree of culpability" as not suitable in this rule. "Culpa" is a civil law term meaning "actionable negligence" (Bryan A. Garner A Dictionary of Modern Legal Usage, Second Edition, Oxford University Press, 1995). WTG opposed the use of any word so strong as to input actionable negligence on their part. The civil liability consequences are too extensive. WTG recommended that subsection (b)(4) be eliminated from the rule. The Commission could substitute "reasonable care" for "culpability." It is not necessary to saddle anyone with the extra liability in a civil lawsuit by using "culpability." As noted in the Commission's response to WTG's previous comment, "degree of culpability" is one of the factors the Commission is required by statute to consider in determining the amount of any penalty for a violation of a provision of this title or a rule, order, license, permit, or certificate that relates to pipeline safety. Because "degree of culpability" is a statutory standard, the Commission has determined that it is appropriately included in the rule.

Air Products recommended deleting §18.12(c), but did not explain its reasons. TxDOT commented that because this subsection removes a person's opportunities once a hearing is convened, it reads like a coercive measure used to discourage someone from fighting a penalty. Additionally, the referenced reduction enhancements are not defined. The Commission disagrees with deleting this provision because it is the policy of the agency to promote settlement in enforcement matters. The reduction is applied only to the basic monetary penalty amount requested and not to any requested enhancements; it is found on line 18, before the lines for penalty enhancements on lines 20 through 25. The next-to-last item, however, is for any reduction in the penalty amount for the demonstrated good faith of the person charged. "Good faith" is explained in §18.12(d).

The Smalley Foundation encouraged the generous application of non-monetary penalties such as safety training classes for first-time or nominal offenders, recognizing that most pipeline damage is caused by third parties. However, the Smalley Foundation trainers are out in the field, so to speak, and they are also aware that many excavators who cause such damage--especially novice or small business owners--fail to report their mistakes due to fear or misinformation concerning the consequences. In the opinion of the Smalley Foundation, mandatory attendance at safety training classes, rather than a fine, is a better solution for these offenders. Also, such classes have a collateral effect, in that it will help spread accurate information to other persons and excavators in particular. Thus, the Foundation especially favored the provision in the rules allowing for this educational option. The Commission agrees that improved education is a benefit with respect to underground pipeline damage prevention.

WTG commented that the penalty amounts shown on Table 1 are too high and clearly show that a penalty will be imposed for every violation. WTG recommended that suggested penalty column of the Penalty Calculations Worksheet be eliminated. The suggested penalties establish a minimum penalty and eliminate the factors stated in the penalty guidelines of subsection (b). There will be occasions that lesser penalties could be accessed after review of the individual case, but suggested penalties creates a minimum penalty that the Commission should avoid. It is only fair to pipeline operators and excavators that the guidelines not end up as an administrative tool to automatically determine the

fine without regard to the actual facts and circumstances of the case. WTG believes it would be wiser to eliminate the suggested penalty column and let the precedent of penalty cases be the guidelines for assessing penalties.

The Commission disagrees with these comments. New §18.12 complies with the requirements of Texas Natural Resources Code, §81.0531, and Texas Utilities Code, §121.206, as explained in previous paragraphs. The recommended penalty amounts are only that; the Commission retains full discretion to assess administrative penalties in any amount up to the statutory maximum when warranted by the facts in any case, or to impose a non-monetary penalty in the form of a warning or a requirement to attend training. An entity that objects to a penalty or disputes the facts of an alleged violation would have an opportunity for an evidentiary hearing pursuant to the Administrative Procedure Act and the Commission's Practice and Procedure rules. The Commission declines to make the changes suggested by WTG because Table 1 is structured as required by the referenced statutory provisions.

WTG also expressed concern about line item no. 11 "failure to provide adequate response" on the calculation worksheet and the amount of $2,500 which is the highest recommended penalty. This is a punitive number directed solely at pipeline operators. Although §18.5 refers to excavators in the title, the actionable provision is subsection (a), which is directed at operators, and the rule does not require an excavator to make a positive response. If this penalty is also directed towards excavators, the worksheet should say so.

The Commission, in agreement with other comments, has already made all recommended penalty amounts equal at $1,000, at least initially. The obligation to make a positive response does belong to operators, and failure to do so is a serious violation. New §18.5 refers to excavators in the title because the rule requires both an operator and an excavator to retain a record of the positive response; however, an excavator's failure to retain such a record is clearly a much less serious violation of the rule than would be an operator's failure to make a positive response.

With respect to §18.12, Atmos submitted that the penalty guidelines lack parity between the operator and the excavator. While Atmos strives daily to mark its facilities accurately and promptly, with the volume of locate activity Atmos is required to undertake, it is likely that over the course of weeks and months, numerous line location issues will arise. For example, in 2006 Atmos performed over 1,100,000 lines locates in Texas. Based upon an internal analysis of damage claims related to those line locates and applying the proposed penalty structure, Atmos estimates that in 2006 it could have been assessed penalties for more than $1,600,000. While it is unclear from the proposed penalty schedule whether the triple, quadruple, and quintuple penalty enhancers (lines 23 through 25 as proposed; lines 22 through 24 as adopted) must relate to the line location event at hand or are cumulative of all prior violations by the excavator or operator, if the enhancers are cumulative of prior violations, the Atmos potential penalty assessment for 2006 would be nearly $7,000,000. Atmos understands that the purpose of penalties is to incent behavior, but the effect of the penalties at these levels will be to cripple an industry.

One behavior that Atmos identified as needing to be addressed aggressively is the liberal use of the "emergency" line locate request. Atmos suggested that a methodology be established for reporting a locate request that is designated as an emergency, but which is not an emergency in view of the operator. There is a suggested penalty for this inappropriate action, but no corresponding reporting mechanism.

Atmos questioned why the failure to provide a positive response carries a suggested penalty that is two and one-half times as much as than the failure to mark a facility properly or the failure to dig with care when most assuredly the failure to mark and the failure to dig with care create far greater safety concerns.

Finally, Atmos suggested that the suggested penalties be reduced to 50 percent of the proposed level. For small excavators, a $1,000 penalty could seriously impact the excavator's business. If experience shows that the level of penalties is an insufficient motivator towards compliance, the Commission can always amend the rule to provide for higher penalties.

The Commission disagrees with Atmos's comments. New §18.12 does not require the imposition of a monetary penalty for every violation. In response to previous comments, the Commission adopts §18.12 with identical recommended penalties for all violations ($1,000), but would point out that the reason for proposing an penalty of $2,500 for failure to provide a positive response is that those failures are so widespread, a situation that might also explain the perceived over-use of emergency line locate requests. The Commission is not adopting the new rules in Chapter 18 in order to penalize every violation it finds. To the contrary, the centerpiece of the new rules is the reporting mechanism, which the Commission expect will provide better data to evaluate the efficacy of the rules in Chapter 18.

Finally, the Commission has reconsidered its proposal to penalize the false reporting of an emergency locate request. The Commission has determined that, ultimately, it is within the purview of the Texas One Call Board to determine and enforce standards for emergency locate requests. The false emergency locate requests are clearly a resource issue for operators, but not of the same magnitude, in terms of safety, as failure to locate, failure to make a positive response, or failure to give notice of intent to excavate. The Commission has removed the penalty proposed in Table 1, line 2.

CenterPoint recommended adding a new penalty to address situations where the excavator does not accurately identify the location of its excavation as required by Section 18.3. The Commission disagrees with this recommendation because it is unnecessary.

CenterPoint suggested that renumbered enhancement item nos. 24-27 (adopted as 23-26) be reexamined and revised to insure that they do not unfairly penalize large operators such as CenterPoint. The Commission disagrees with making this change because of having added to §18.12(b)(6) as a factor to be considered the number of line locate requests received each year.

TGA commented on Table 1, Line 1, the recommended penalty of $1,000 for failure to comply with Chapter 18. TGA stated that assuming that *any* damage to a pipeline would be addressed under Line No. 1 B *"Failure to comply with Chapter 18,"* the Commission must exercise discretion in assessing penalties to excavators who report the damage to the operator. Currently, many excavators who inadvertently damage a located pipeline contact the operator who then makes the appropriate repair to the damage. Should penalties be enforced for those damages, the results could be the unintended consequence of reducing the number of damages reported to the operator. If the damages are not reported and therefore not repaired, the results could be significantly worse. Covering up a small damage to avoid a

penalty would result in a continuing potential for an incident or accident, negating the very rationale for this rule.

The Commission agrees that there is a balance to be struck between enforcing the provisions of Chapter 18 and creating disincentives for excavators to report damage to an operator so that the operator can make a timely repair. The Commission has stated, in response to other comments, that not every violation of the Chapter 18 rules will necessarily result in an enforcement action, and not every enforcement action will necessarily result in monetary penalties. The Commission acknowledges and encourages the cooperative relationships that operators and excavators have developed that promote timely reporting and prompt repair of damage to underground pipelines.

Air Products commented that the penalty in Table 1, Line 3, failure to notify notification center, should have a penalty of $2,500, instead of the $1,000 that was proposed. The Commission disagrees, having adjusted all recommended penalties in Table 1 to $1,000 in response to other comments.

Air Products also asked how the penalty shown in Table 1, line 5, failure to use white-lining where appropriate, was to be judged, then recommended a zero penalty amount. The Commission disagrees with the suggestion to reduce the recommended penalty to zero, and offers the following clarification to the requirement in §18.3 regarding use of white-lining. If an operator is unable to determine from a locate ticket where an excavation is going to take place, then the excavator would be required to use white-lining. If the operator is still unable to determine where to place the location markings, then that may be an indication that the excavator has failed to use white-lining where it was necessary.

Air Products commented that there should not be a penalty for failure to report damage by third party (Table 1, line 16) because, operators will be motivated naturally to provide notification. The Commission disagrees. The Commission wants reports of all damage to underground pipelines in order to be able to analyze which types of damage are most common, whether the rules in Chapter 18 are adequate to notify excavators and operators of safe practices, and whether and what additional steps might be taken to improve pipeline safety.

Air Products recommended eliminating line 18 on Table 1, the reduction for settlement before hearing: up to 50 percent of the amount shown on line 17, but did not explain the reason for this recommendation. The Commission disagrees with it; it is the policy of the Commission to encourage settlement of enforcement actions.

Texas Gas expressed concern with the penalty enhancements found on lines 22 through 25 of Table 1. These penalty enhancements double, triple, quadruple and even quintuple penalty amounts for repeat infractions. Presumably these enhancements are intended to create incentives for excavators and operators to carefully follow the rules, and Texas Gas applauds this intent. Texas Gas worried, however, that including these categories in a worksheet for calculating fines runs the risk of multiplying penalties for repeat infractions as a matter of course, without regard to the culpability of the underlying conduct. Texas Gas operates 15,412 miles of pipelines and services throughout the state and receives on average more than 145,000 line locate requests in a given year. Given the sheer volume of line locates, even a scrupulously prudent and attentive operator will surely run afoul of one or more rules on multiple occasions. For instance, even if Texas Gas successfully complies with all rules on 99.9 percent of line locate requests, this still leaves 145 infractions. Texas Gas does not believe it is reasonable to double, triple, or even quintuple the penalties as a matter of course for mistakes that cannot be reasonably prevented. The enhancements cannot change Texas Gas' conduct to any greater extent, and therefore have no policy justification and instead act as a hidden tax on the utility. Texas Gas therefore recommends deleting those penalty enhancements from the penalty worksheet.

To the extent an enhancement for repeat infractions is merited, whether for excavator or operator, the rules already specify that consideration be given to "the person's history of previous violations, including the number of previous violations" (proposed §18.12(b)(1)). Thus, the Commission is authorized to enhance a penalty for repeat offenders when the circumstances of the infraction merit the enhancement. Given that the rule already contemplates a subjective analysis of a party's compliance history, Texas Gas objects to the inclusion of specific language in the penalty calculation worksheet enhancing penalties for repeat infractions.

With respect to the penalty enhancements shown on Table 1, lines 22-25, Texas Gas commented that operators who receive locate tickets from several excavators have a geometrically-larger number of locates than the individual excavators have notifications of excavations to the notification center. The penalties for both the operator and the excavator are based on arithmetic progressions. Therefore the operator stands to have a larger number of penalties than the excavator for the same number of violations. If the enhancement portion of the penalties could be based upon a percentage or some other means that would equalize the number of actions (notifications or locates), the enhancement section of the rule would be more equitable between the operators and the excavators.

The Commission disagrees with this comment. The rule itself does not mandate penalties for every violation of the Chapter 18 rules; nor does it require monetary penalties for violations. The Commission has added to §18.12(b)(6) as a factor to be considered the number of line locate requests received each year. The rate of compliance will also be a component of "demonstrated good faith," a mitigating consideration under §18.12(b)(5). Finally, Texas Natural Resources Code, §81.0531, and Texas Utilities Code, §121.206, expressly require the Commission to adopt, by rule, guidelines to be used in determining the amount of the penalty for a violation of a provision a rule, order, license, permit, or certificate that relates to pipeline safety. The guidelines are expressly required to include a penalty calculation worksheet that specifies the typical penalty for certain violations, the circumstances justifying enhancement of a penalty and the amount of the enhancement, and the circumstances justifying a reduction in a penalty and the amount of the reduction. By statute, the guidelines must take into account the permittee's history of previous violations, including the number of previous violations; the seriousness of the violation and of any pollution resulting from the violation; any hazard to the health or safety of the public; the degree of culpability; the demonstrated good faith of the person charged; and any other factor the Commission considers relevant.

Air Products asked the time period over which the previous violations would be considered. The Commission will consider all prior violations, but the time period over which those have occurred would also be taken into account. For example, an entity that had two prior violations in the past five years would be

viewed differently from an entity that had two prior violations in the past six months.

SM&P believed that the suggested rules and the fines associated with them will have an undesirable destabilizing effect on the safety and effectiveness of utility locating. This is particularly the case in reference to fine amounts shown on Table 1, lines 21-25, which escalate fines to levels which would become prohibitively burdensome. In SM&P's view, the Commission's proposed definition of "persons" would be unduly burdensome to larger operators and locating companies who would have a disproportionate amount of tickets compared to others over the course of a year. SM&P believed that the fines listed in the Penalty Calculation Worksheet should be removed from the proposed rule changes. In the alternative, SM&P recommended that the penalties shown on lines 4, 6, and 7 should be removed, consistent with other comments made by SM&P, and the recommended penalty on line 1 should be removed as redundant. The Commission reiterates the response made to similar comments by Texas Gas and Air Products in previous paragraphs.

As adopted, new §18.1, relating to scope, applicability, and general provisions, sets forth the statutory basis for the new rules in Chapter 18. The chapter implements the authority of the Commission under Texas Natural Resources Code, §117.012, and Texas Utilities Code, §121.201 (as amended by House Bill 2161, Acts 2005, 79th Leg., R.S., ch. 267, §§6 and 13, eff. Sept. 1, 2005), and under Texas Health and Safety Code, §756.106 (as added by Senate Bill 9, Acts 2005, 79th Leg., R. S., ch. 1337, §19, and editorially renumbered as Health and Safety Code, §756.126). Except as provided in subsection (d) of this section, this chapter applies to all persons engaged in or preparing to engage in the movement of earth in the vicinity of an intrastate underground pipeline containing flammable, toxic, or corrosive gas, a hazardous liquid, or carbon dioxide.

The requirements of the new rules in Chapter 18 are based on the presumption that an excavator will notify a notification center pursuant to, and that a pipeline operator will respond in accordance with, the provisions of Texas Utilities Code, Chapter 251, and the requirements of the notification center. However, compliance with the provisions of Texas Utilities Code, Chapter 251, and the requirements of a notification center does not necessarily constitute compliance with the requirements of this chapter.

Persons that are exempt from the provisions of Texas Utilities Code, Chapter 251, are required to comply with this chapter, unless the person is exempt under the subsection (d) of §18.1. Subsection (d) declares that this chapter does not apply to: (1) the exemptions in Texas Utilities Code, §251.003; (2) the movement of earth that does not exceed a depth of 16 inches; or (3) surface mining operations. The Commission adopts new subsection (d) with additional exemptions for specific TxDOT activities, having found that the exemptions are in the public interest and are not likely to cause harm to the safety and welfare of the public. The following activities when performed by an employee of TxDOT within TxDOT right-of-way, are exempt from the requirements of Chapter 18: sampling and repair of pavement, base, and subgrade; repair of roadway embankment adjacent to pavement structure; reshaping of unpaved shoulders and drop-offs; installation and maintenance of guardrails, cable barriers, delineators, vehicle attenuators, sign posts, mailboxes, and cables for traffic signals and luminaries; cleaning of ditches; and removal of silt from culverts. Additionally, hand digging by an employee or contractor of TxDOT for TxDOT's archeological program is exempt.

Additional general provisions in new §18.1 include an express statement that this chapter applies to movement of earth by tillage that exceeds a depth of 16 inches. Unless otherwise specified, all time periods used in this chapter are to be calculated from the time the original notification is given to the notification center. Also, unless otherwise specified, all time periods that are stated in days shall mean working days. Unless an excavator and an operator otherwise expressly agree in accordance with the requirements set forth in new §18.3, the life of a line locate ticket shall is 14 days. Finally, unless otherwise expressly stated in Chapter 18, each excavator and each operator shall retain required records for at least four years. At a minimum, each operator and each excavator must retain locate tickets and positive response notifications. Retention at a notification center is an acceptable method of retention for locate tickets.

As adopted, new §18.2, relating to definitions, includes clarifying amendments to the proposed definition for "emergency," which is defined as a situation that endangers life, health, or property or a situation in which the public need for uninterrupted service and immediate re-establishment of service if services are interrupted compels immediate action. This is consistent with the definition found in Texas Utilities Code, Chapter 251.

The Commission adopts the definition of the term "notification center" with a clarifying amendment to mean a legal entity established and operated pursuant to Texas Utilities Code, Chapter 251, Subchapter C.

The Commission adopts the definition of "positive response" with clarifying amendments to remove the word "planned" from the description of excavations in the vicinity of underground pipelines; to include specific reference to use of fax, phone, e-mail, pager, or written correspondence; and to remove the phrase "other shared or transmitted information."

The Commission adopts the definition of "tillage" with a minor modification to remove the phrase "into a desired condition."

The Commission adopts the definition of "tolerance zone" with a clarifying amendment that removes the word "width" and substitutes the term "nominal diameter."

The Commission adopts all other definitions as proposed.

The Commission adopts new §18.3, relating to excavator notice to notification center, with clarifying changes. An excavator must request the location of underground pipelines at each excavation site by giving notice to the notification center as required by Texas Utilities Code, Chapter 251, and must include in the notice the method or methods by which the excavator will receive a positive response. When an excavation site cannot be clearly identified and described on a line locate ticket, the excavator must use white-lining to mark the excavation area prior to giving notice to the notification center and before the locator arrives on the excavation site. If an excavation project is too large to mark using white-lining or is so expansive that a full description cannot be provided on a line locate ticket, then the operator and the excavator are required to conduct a face-to-face meeting to discuss the excavation activities and to establish protocols for (1) the interval between each notice to the notification center; (2) the scope of each line locate ticket; (3) the life of each line locate ticket; and (4) the schedule of work on the excavation and the chronological order in which applicable locate tickets are to be marked. If an excavation project is not completed at the time a line locate ticket expires, the excavator must refresh the ticket by giving the notice described in subsection (a) of this section,

but the request to refresh must be limited to the area yet to be excavated. An excavator and an operator may agree that the life of a line locate ticket is more than 14 days provided that the agreement is in writing and the agreement is signed and dated by both the excavator and the operator. Both the excavator and the operator must retain a copy of any such agreement.

The Commission adopts new §18.4, relating to excavator obligation to avoid damage to underground pipelines, with clarifying changes in subsection (d) and (f) and a new subsection (h). An excavator must comply with the requirements of §18.3, relating to excavator notice to notification center. An excavator must also comply with the requirements of Texas Health & Safety Code, Subchapter H, relating to Construction Affecting Pipeline Easements and Rights-of-Way, and must plan an excavation in such a manner as to avoid damage to and minimize interference with all underground pipelines in the vicinity of the excavation area and take all reasonable steps to protect underground pipelines from damage. An excavator shall wait the time required by Texas Utilities Code, Chapter 251, before beginning excavation.

Prior to excavation, an excavator must confirm that a copy of a valid locate ticket for the location is in the possession of the excavator's designated representative and can be obtained from the representative or can be provided within one hour of a request from the operator or the Commission. Prior to excavation, an excavator must verify that it is at the correct location as specified on the locate ticket; verify white-lining; and, to the best of the excavator's ability, make a visual check for any unmarked underground pipelines. Checking for unmarked underground pipelines includes, but is not limited to looking for additional pipeline line markers, such as painted fence post-type markers, aboveground pipeline valves, meter sets, regulator stations, or rectifier units. An excavator may not begin excavating until a second notice is given to the notification center for the area if (1) the excavator has knowledge of the existence of an underground pipeline and has received an "all clear" or a "no conflict" response from an operator; (2) the excavator observes clear evidence (such as a line marker or an above-ground fixture) of the presence of an unmarked underground pipeline in the area of the proposed excavation, and has received an "all clear" or a "no conflict" response from an operator; (3) there is no positive response for the excavation area; or (4) the positive response is unclear or obviously erroneous (for example, for a different location or for a different type of underground facility). If an excavator has given a second notice in accordance with this section and there is no positive response within four hours, the excavator may begin excavating. An excavator must protect and preserve locate markings from the time the excavator begins work until markings are no longer required for the proper and safe excavation in the vicinity of all underground pipelines. Finally, each excavator that damages an underground pipeline must notify the operator of the damage through the notification center immediately but not later than two hours following the damage incident, and may not cover the exposed pipeline without approval of the operator.

The Commission adopts new §18.5, relating to operator and excavator obligations with respect to positive response, with clarifying changes in subsection (c) and a new subsection (d). Upon being contacted by the notification system, an operator must provide a positive response within the time frames specified in Texas Utilities Code, Chapter 251, by either (1) marking the operator's underground pipelines in accordance with the requirements of Texas Utilities Code, Chapter 251, and this chapter; or (2) notifying the excavator that the operator has no underground pipelines in the vicinity of the proposed excavation area. The operator must provide this "all clear" or "no conflict" notice using the method or methods that the excavator specified. Both the excavator and the operator must make a record of the positive response regarding each line locate ticket received.

An excavator that gives a second notice to the notification center because an operator failed to provide a positive response to an excavator must report that fact to the Commission through TDRF as set forth in new §18.11. An excavator must also report an operator's failure to provide a positive response to a second call to the Commission through TDRF. An operator that receives a notice of damage to its underground pipeline through a notification center pursuant to §18.11(b) must respond within four hours.

The Commission adopts new §18.6, relating to general marking requirements, with clarifying changes in subsections (b) and (c). At a minimum, all markings must conform to the requirements of American Public Works Association (APWA) Uniform Color Code (ANSI Standard Z535.1, Safety Color Code). Markings must be valid for an excavation site for 14 days from the time a positive response is given, unless the markings were placed in response to an emergency and the emergency condition has ceased to exist. If a line locate ticket has been refreshed, then the operator must either ensure that markings are still visible and valid or must re-mark. If the use of line marking may permanently damage property (driveways, landscaping, historic locations to the extent boundaries are known), a locator must use spot marking or another suitable marking method or methods.

The Commission adopts new §18.7, relating to excavator marking requirements, with clarifying changes in subsection (a). Prior to giving notice pursuant to new §18.3, an excavator must mark, if applicable according to §18.3(c), the specific excavation area using white paint flags, or stakes, whichever is most visible for the terrain. An excavator must mark the area of excavation using intervals that show the direction of the excavation.

The Commission adopts new §18.8, relating to operator marking requirements. A locator must use all information necessary to mark underground pipelines accurately, and must mark the approximate center line of an underground pipeline. If, in the process of marking an underground pipeline, a locator discovers a customer-owned underground pipeline, the locator is required to make a reasonable effort to advise the excavator of the presence of the customer-owned underground pipeline. Where a proposed excavation crosses an underground pipeline, markings must be at intervals that clearly define the route of the underground pipeline, to the extent possible. A locator must mark underground pipelines by means of stakes, paint, flags, or a combination of two or more of these. The terrain, site conditions, and type and extent of the proposed excavation must be considered in determining the most suitable means for marking underground pipelines. In addition, a locator must mark at sufficient intervals to indicate clearly the approximate horizontal location and direction of the underground pipeline or pipelines. The distance between any two marks indicating the same line must not exceed 20 feet; however, a shorter distance between marks may be necessary because of site conditions or directional changes of the underground pipeline. Markings of an underground pipeline greater than six inches in nominal outside dimension must include the size in inches at every other mark. A locator must extend all markings, if practical, at least one additional mark beyond the boundaries of the specific location of the proposed work as detailed on the line locate ticket. A locator must make paint marks approximately eight to ten inches in length and one to two inches in width except when spot mark-

ing is necessary, and must make a minimum of three separate marks for each underground pipeline marking.

The Commission adopts new §18.9, relating to options for managing an excavation site in the vicinity of an underground pipeline, with clarifying changes in subsection (a). After complying with the notice requirements of new §18.3, an excavator and an operator may jointly establish the protocols applicable to an excavation site in the vicinity of underground pipelines based on the particular characteristics of each job. The protocols applicable to an excavation site may designate the contact person or persons for each entity working at an excavation site; establish the required mode or modes of communication among all entities working at an excavation site, e.g., telephone or other electronic means or face-to-face meetings at prescribed times or intervals; provide the method for coordinating work activities among all entities working at an excavation site; provide for the ownership and/or possession of the locate ticket or tickets; declare which entity or entities must have the locate ticket or locate ticket number before beginning work; state the life of a locate ticket and the circumstances that require refreshing the locate ticket; state the schedule of work on the excavation and, if applicable, the chronological order in which applicable locate tickets are to be located; designate the extent of the tolerance zone, provided that it may not be less than half the nominal diameter of the underground pipeline plus a minimum of 18 inches on either side of the outside edge of the underground pipeline on a horizontal plane, and the type of excavation permitted within the tolerance zone; and provide for any other agreement with respect to excavation activities and/or marking requirements that will or will tend to ensure the proper and safe excavation in the vicinity of an underground pipeline. If an excavator and an operator jointly establish protocols pursuant to this section, both the excavator and the operator must make and retain a record of the agreement.

The Commission adopts new §18.10, relating to excavation within tolerance zone, with a clarifying change to subsection (b). An excavator must comply with the requirements of Texas Health & Safety Code, Subchapter H, relating to Construction Affecting Pipeline Easements and Rights-of-Way. When excavation is to take place within the specified tolerance zone, an excavator must exercise such reasonable care as may be necessary to prevent damage to any underground pipeline in or near the excavation area. Methods to consider, based on certain climate or geographical conditions, include hand digging when practical, soft digging, vacuum excavation methods, pneumatic hand tools. Other mechanical methods or other technical methods that may be developed may be used with the approval of the underground pipeline operator. Hand digging and non-invasive methods are not required for pavement removal.

The Commission adopts new §18.11, relating to reporting requirements, with clarifying changes. Each operator of an underground pipeline must report to the Commission all damage to its pipelines caused by an excavator. Within 10 days of the damage incident or of the operator's actual knowledge of the damage incident, an operator is required to submit the information to the Commission through TDRF, which may be accessed at http://www.rrc.state.tx.us/formpr/index.html using its assigned operator identification code.

Each excavator that damages an underground pipeline must notify the operator of the damage through the notification center within two hours following the damage incident. The excavator must also submit report of the damage incident to the Commission using TDRF, within 10 days of the incident. Each excavator that makes an additional call to the notification center because the excavator did not receive a positive response to an initial notice must report that fact to the Commission through TDRF. An excavator must also report an operator's failure to provide a positive response to a second call to the Commission through TDRF.

An emergency response official, a member of the general public, or another person aware of damage to an underground pipeline is encouraged to submit an incident form using TDRF. Entries can be made through the general public or emergency response official sign-in.

The Commission adopts new §18.12, relating to penalty guidelines, with clarifying changes in subsection (b) and to Table 1, and the deletion of the last sentence of subsection (e) because of changes made in subsection (b)(1). The penalty amounts shown in the table in this section are provided solely as guidelines to be considered by the Commission in determining the amount of administrative penalties for violations of the requirements of this chapter. The establishment of these penalty guidelines in no way limits the Commission's authority and discretion to assess administrative penalties in any amount up to the statutory maximum when warranted by the facts in any case. The amount of any penalty requested, recommended, or finally assessed in an enforcement action will be determined on an individual case-by-case basis for each violation, taking into consideration the following factors: (1) the person's history of previous violations or formal warnings, including the number of previous violations or formal warnings; (2) the seriousness of the violation and of any pollution resulting from the violation; (3) any hazard to the health or safety of the public; (4) the degree of culpability; (5) the demonstrated good faith of the person charged; and (6) any other factor the Commission considers relevant, including but not limited to the number of locate requests received and responded to by an operator and the number of location notifications given by an excavator in the previous year.

The recommended monetary penalty for a violation may be reduced by up to 50 percent if the person charged agrees to a settlement before the Commission conducts an administrative hearing to prosecute a violation. Once the hearing is convened, the opportunity for the person charged to reduce the basic monetary penalty is no longer available. The reduction applies to the basic monetary penalty amount requested and not to any requested enhancements.

In determining the total amount of any monetary penalty requested, recommended, or finally assessed in an enforcement action, the Commission may consider, on an individual case-by-case basis for each violation, the demonstrated good faith of the person charged. Demonstrated good faith includes, but is not limited to, actions taken by the person charged before the filing of an enforcement action to remedy, in whole or in part, a violation of the rules in this chapter or to mitigate the consequences of a violation of the rules in this chapter.

Depending upon the nature of and the consequences resulting from a violation of this chapter, the Commission may impose a non-monetary penalty, such as requiring attendance at a safety training course, or may issue a warning.

In Table 1, the Commission has established recommended penalty amounts of $1,000 for all violations of the rules in Chapter 18, has removed the proposed penalty for a false report of emergency line locate request, and has made minor wording clarifications in specific items.

The Commission adopts the new sections pursuant to Texas Natural Resources Code, §§81.0531 and 117.012, and Texas Utilities Code, §§121.201 (as amended by House Bill 2161, Acts 2005, 79th Leg., R.S., ch. 267, §§6 and 13, eff. Sept. 1, 2005), and 121.206. As amended, Texas Natural Resources Code, §117.012, provides that the Commission shall adopt rules that include safety standards for and practices applicable to the intrastate transportation of hazardous liquids or carbon dioxide by pipeline and intrastate hazardous liquid or carbon dioxide pipeline facilities, including safety standards related to the prevention of damage to such a facility resulting from the movement of earth by a person in the vicinity of the facility, other than movement by tillage that does not exceed a depth of 16 inches. As amended, Texas Utilities Code, §121.201(a)(1), states that the Commission may by rule prescribe or adopt safety standards for the transportation of gas and for gas pipeline facilities, including safety standards related to the prevention of damage to such a facility resulting from the movement of earth by a person in the vicinity of the facility, other than movement by tillage that does not exceed a depth of 16 inches. In addition, by adopting the new rules in Chapter 18, the Commission is implementing the authority delegated by and under Texas Health and Safety Code, §756.106 (as added by Senate Bill 9, Acts 2005, 79th Leg., R. S., ch. 1337, §19, and editorially renumbered as Health and Safety Code, §756.126). This new provision states that the Commission shall adopt and enforce safety standards and best practices, including those described by 49 U.S.C. §6105 et seq., relating to the prevention of damage by a person to a facility under the jurisdiction of the Commission. With some stated exceptions, the proposed new rules would apply to all persons engaged in or preparing to engage in the movement of earth in the vicinity of an intrastate underground pipeline containing flammable, toxic, or corrosive gas, a hazardous liquid, or carbon dioxide. Texas Natural Resources Code, §81.0531, and Texas Utilities Code, §121.206, require the Commission by rule to adopt guidelines to be used in determining the amount of the penalty for a violation of a provision of a statute or a rule that relates to pipeline safety. The guidelines must include a penalty calculation worksheet that specifies the typical penalty for certain violations, circumstances justifying enhancement of a penalty and the amount of the enhancement, and circumstances justifying a reduction in a penalty and the amount of the reduction. The guidelines must also take into account: (1) the permittee's history of previous violations, including the number of previous violations; (2) the seriousness of the violation and of any pollution resulting from the violation; (3) any hazard to the health or safety of the public; (4) the degree of culpability; (5) the demonstrated good faith of the person charged; and (6) any other factor the Commission considers relevant.

Texas Natural Resources Code, §§81.0531 and 117.012; Texas Utilities Code, §§121.201 and 121.206; and Texas Health and Safety Code, §756.126, are affected by the proposed new rules.

Statutory authority: Texas Natural Resources Code, §§81.0531 and 117.012; Texas Utilities Code, §§121.201 and 121.206; and Texas Health and Safety Code, §756.126.

Cross-reference to statute: Texas Natural Resources Code, §§81.0531 and 117.012; Texas Utilities Code, §§121.201 and 121.206; and Texas Health and Safety Code, §756.126.

Issued in Austin, Texas, on May 30, 2007.

§18.1. Scope, Applicability, and General Provisions.

(a) This chapter implements the authority of the Railroad Commission of Texas (Commission) under Texas Natural Resources Code, §117.012, and Texas Utilities Code, §121.201 (as amended by House Bill 2161, Acts 2005, 79th Leg., R.S., ch. 267, §§6 and 13, eff. Sept. 1, 2005), and under Texas Health and Safety Code, §756.106 (as added by Senate Bill 9, Acts 2005, 79th Leg., R. S., ch. 1337, §19, and editorially renumbered as Health and Safety Code, §756.126). Except as provided in subsection (d) of this section, this chapter applies to all persons engaged in or preparing to engage in the movement of earth in the vicinity of an intrastate underground pipeline containing flammable, toxic, or corrosive gas, a hazardous liquid, or carbon dioxide.

(b) The requirements of this chapter are based on the presumption that an excavator will notify a notification center pursuant to, and that a pipeline operator will respond in accordance with, the provisions of Texas Utilities Code, Chapter 251, and the requirements of the notification center. However, compliance with the provisions of Texas Utilities Code, Chapter 251, and the requirements of a notification center does not necessarily constitute compliance with the requirements of this chapter.

(c) Persons that are exempt from the provisions of Texas Utilities Code, Chapter 251, are required to comply with this chapter, unless the person is exempt under the subsection (d) of this section.

(d) This chapter does not apply to:

(1) the exemptions in Texas Utilities Code, §251.003;

(2) the movement of earth that does not exceed a depth of 16 inches;

(3) surface mining operations;

(4) the following activities when performed by an employee of TxDOT within TxDOT right-of-way:

(A) sampling and repair of pavement, base, and subgrade;

(B) repair of roadway embankment adjacent to pavement structure;

(C) reshaping of unpaved shoulders and drop-offs;

(D) installation and maintenance of guardrails, cable barriers, delineators, vehicle attenuators, sign posts, mailboxes, and cables for traffic signals and luminaries;

(E) cleaning of ditches; and

(F) removal of silt from culverts; or

(5) hand digging by an employee or contractor of TxDOT for TxDOT's archeological program.

(e) This chapter also applies to movement of earth by tillage that exceeds a depth of 16 inches.

(f) Unless otherwise specified, all time periods used in this chapter shall be calculated from the time the original notification is given to the notification center.

(g) Unless otherwise specified, all time periods that are stated in days shall mean working days.

(h) Unless an excavator and an operator otherwise expressly agree in accordance with the requirements set forth in §18.3 of this title, relating to Excavator Notice to Notification Center, the life of a line locate ticket shall be 14 days.

(i) Unless otherwise expressly stated in this chapter, each excavator and each operator shall retain required records for at least four years. At a minimum, each operator and each excavator shall retain

locate tickets and positive response notifications. Retention at a notification center is an acceptable method of retention for locate tickets.

§18.2. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

(1) Damage--Includes but is not limited to:

(A) defacing, scraping, displacement, penetration, destruction, or partial or complete severance of an underground pipeline or of any protective coating, housing, or other protective device of an underground pipeline;

(B) weakening of structural or lateral support of an underground pipeline that affects the integrity of the pipeline; or

(C) failure to properly replace the backfill surrounding an underground pipeline.

(2) Demolish or demolition--Any operation by which a structure or mass of material is wrecked, razed, rendered, moved, or removed by means of any tools, equipment, or discharge of explosives.

(3) Emergency--A situation that endangers life, health, or property or a situation in which the public need for uninterrupted service and immediate re-establishment of service if services are interrupted compels immediate action.

(4) Excavate--Movement of earth by any means.

(5) Excavator--A person that engages in or is preparing to engage in the movement of earth.

(6) Hand digging--Any movement of earth using non-mechanized tools or equipment, soft digging, or vacuum excavation. Hand digging includes but is not limited to digging with shovels, picks, and manual post hole diggers.

(7) Legal holiday--A holiday specified as a legal holiday by Subchapter B, Chapter 662, Texas Government Code.

(8) Locate or marking--An operator's or its contract locator's physical demarcation of the location of an underground pipeline.

(9) Locate ticket, line locate ticket, or ticket--The record of the notice of intent to excavate given by an excavator to a notification center in conformance with Texas Utilities Code, §§251.151 and 251.152.

(10) Locator--A person charged with determining and marking the approximate horizontal location of underground pipeline that may exist within an area either specified by a notice served on a notification center or designated by white-lining.

(11) Movement of earth--Any operation in which earth, rock, or other material in the ground, any structure, or any mass of material is moved, removed, disturbed, or otherwise displaced by hand digging, mechanized equipment or tools of any kind, or explosives, and includes but is not limited to augering, backfilling, boring, cable or pipe plowing and driving, compressing, cutting, demolition, digging, ditching, dragging, dredging, drilling, grading, plowing-in, pulling-in, razing, rendering, ripping, scraping, tilling of earth at a depth exceeding 16 inches, trenching, tunneling, or wrecking.

(12) Mechanized equipment or tool--A piece of equipment or a tool operated by mechanical power, including but not limited to a tractor, trencher, bulldozer, power shovel, auger, backhoe, scraper, drill, cable or pipe plow and/or driver, and other equipment used to plow in or pull in cable or pipe.

(13) Notification center--A legal entity established and operated pursuant to Texas Utilities Code, Chapter 251, Subchapter C.

(14) Notify, notice, or notification--The completed delivery of information to the person to be notified, and the receipt of that information by that person in accordance with this chapter. The delivery of information includes but is not limited to the use of any electronic or technological means of data transfer.

(15) Operator--A person who operates on his or her own behalf, or as an agent designated by the owner, a pipeline containing flammable, toxic, or corrosive gas, a hazardous liquid, or carbon dioxide.

(16) Person--Any individual, operator, firm, joint venture, partnership, corporation, association, municipality, or other political subdivision, governmental unit, department or agency, and includes any trustee, receiver, assignee, or personal representative thereof.

(17) Positive response--Notification to an excavator by markings left at an excavation site, or by fax, phone, e-mail, pager, or written correspondence that allows an excavator to know prior to the beginning of excavation that underground pipelines have been located and marked or that there are no underground pipelines in the vicinity of the excavation.

(18) Soft digging--Any movement of earth using tools or equipment that use air or water pressure as the direct means to break up soil or earth for removal by vacuum excavation.

(19) Spot marking--Making a circle around the spot where excavation is to take place, typically used when standard marking techniques would be considered damaging to property or cannot be used because of limited space.

(20) Tillage--The manipulation of soil in preparation for planting and the cultivation by loosening or breaking up of soil around growing plants by hand digging or by use of a moldboard, disk, rotary, chisel or subsoil plow, a cultivator, a harrow, or a tiller.

(21) Tolerance zone--Half the nominal diameter of the underground pipeline plus a minimum of 18 inches on either side of the outside edge of the underground pipeline on a horizontal plane.

(22) TDRF--The Texas Damage Reporting Form, the on-line reporting system of the Railroad Commission for use in reporting damage to underground pipelines or violations of this chapter.

(23) Underground pipeline--A pipeline containing flammable, toxic, or corrosive gas, a hazardous liquid, or carbon dioxide that is located partially or totally underground.

(24) White-lining--An excavator's designation on the ground of the area to be excavated using white paint, white flags, white stakes, or any combination of these.

(25) Working day--Every day that is not a Saturday, a Sunday, or a legal holiday.

§18.3. Excavator Notice to Notification Center.

(a) An excavator shall request the location of underground pipelines at each excavation site by giving notice to the notification center as required by Texas Utilities Code, Chapter 251.

(b) An excavator shall include in the notice the method or methods by which the excavator will receive a positive response.

(c) When an excavation site cannot be clearly identified and described on a line locate ticket, the excavator shall use white-lining to mark the excavation area prior to giving notice to the notification center and before the locator arrives on the excavation site.

(d) If an excavation project is too large to mark using white-lining or is so expansive that a full description cannot be provided on a line locate ticket, then the operator and the excavator shall conduct a

face-to-face meeting to discuss the excavation activities and to establish protocols for:

(1) the interval between each notice to the notification center;

(2) the scope of each line locate ticket;

(3) the life of each line locate ticket; and

(4) the schedule of work on the excavation and the chronological order in which applicable locate tickets are to be marked.

(e) If an excavation project is not completed at the time a line locate ticket expires, the excavator shall refresh the ticket by giving the notice described in subsection (a) of this section. A request to refresh shall be limited to the area yet to be excavated.

(f) An excavator and an operator may agree that the life of a line locate ticket is more than 14 days provided that:

(1) the agreement is in writing; and

(2) the agreement is signed and dated by both the excavator and the operator.

(g) Both the excavator and the operator shall retain a copy of any agreement made pursuant to subsection (f) of this section.

§18.4. Excavator Obligation to Avoid Damage to Underground Pipelines.

(a) An excavator shall comply with the requirements of §18.3 of this title, relating to Excavator Notice to Notification Center. An excavator shall also comply with the requirements of Texas Health & Safety Code, Subchapter H, relating to Construction Affecting Pipeline Easements and Rights-of-Way, and shall plan an excavation in such a manner as to avoid damage to and minimize interference with all underground pipelines in the vicinity of the excavation area and shall take all reasonable steps to protect underground pipelines from damage.

(b) An excavator shall wait the time required by Texas Utilities Code, Chapter 251, before beginning excavation.

(c) Prior to excavation, an excavator shall confirm that a copy of a valid locate ticket for the location is in the possession of the excavator's designated representative and can be obtained from the representative or can be provided within one hour of a request from the operator or the Commission.

(d) Prior to excavation, an excavator shall verify that it is at the correct location as specified on the locate ticket; shall verify white-lining; and, to the best of the excavator's ability, shall make a visual check for any unmarked underground pipelines. Checking for unmarked underground pipelines includes, but is not limited to, looking for additional pipeline line markers, such as painted fence post-type markers, aboveground pipeline valves, meter sets, regulator stations, or rectifier units.

(e) An excavator shall not begin excavating until a second notice is given to the notification center for the area if:

(1) the excavator has knowledge of the existence of an underground pipeline and has received an "all clear" or a "no conflict" response from an operator;

(2) the excavator observes clear evidence (such as a line marker or an above-ground fixture) of the presence of an unmarked underground pipeline in the area of the proposed excavation, and has received an "all clear" or a "no conflict" response from an operator;

(3) there is no positive response for the excavation area; or

(4) the positive response is unclear or obviously erroneous (for example, for a different location or for a different type of underground facility).

(f) If an excavator has given a second notice in accordance with this section and there is no positive response within four hours, the excavator may begin excavating.

(g) An excavator shall protect and preserve locate markings from the time the excavator begins work until markings are no longer required for the proper and safe excavation in the vicinity of all underground pipelines.

(h) Each excavator that damages an underground pipeline shall notify the operator of the damage through the notification center immediately but not later than two hours following the damage incident. An excavator that damages an underground pipeline shall not cover the exposed pipeline without approval of the operator.

§18.5. Operator and Excavator Obligations with Respect to Positive Response.

(a) Upon being contacted by the notification system, an operator shall provide a positive response within the time frames specified in Texas Utilities Code, Chapter 251, by either:

(1) marking the operator's underground pipelines in accordance with the requirements of Texas Utilities Code, Chapter 251, and this chapter; or

(2) notifying the excavator that the operator has no underground pipelines in the vicinity of the proposed excavation area. The operator shall provide this "all clear" or "no conflict" notice using the method or methods that the excavator specified in accordance with §18.3 of this title, relating to Excavator Notice to Notification Center.

(b) Both the excavator and the operator shall make a record of the positive response regarding each line locate ticket received.

(c) An excavator that gives a second notice to the notification center pursuant to §18.4(e) of this title, relating to Excavator Obligation to Avoid Damage to Underground Pipelines, because an operator failed to provide a positive response to an excavator shall report that fact to the Commission through TDRF as set forth in §18.11 of this title, relating to Reporting Requirements. An excavator shall also report an operator's failure to provide a positive response to a second call to the Commission through TDRF as specified in §18.11.

(d) An operator that receives a notice of damage to its underground pipeline through a notification center pursuant to §18.11(b) of this title, relating to reporting requirements, shall respond within four hours.

§18.6. General Marking Requirements.

(a) At a minimum, all markings shall conform to the requirements of American Public Works Association (APWA) Uniform Color Code (ANSI Standard Z535.1, Safety Color Code).

(b) Markings shall be valid for an excavation site for 14 days from the time a positive response is given, unless the markings were placed in response to an emergency and the emergency condition has ceased to exist. If a line locate ticket has been refreshed pursuant to §18.3(e) of this title, relating to Excavator Notice to Notification Center, then the operator shall either ensure that markings are still visible and valid or shall re-mark.

(c) If the use of line marking may permanently damage property (driveways, landscaping, historic locations to the extent boundaries are known), a locator shall use spot marking or another suitable marking method or methods.

§18.7. Excavator Marking Requirements.

(a) Prior to giving notice pursuant to §18.3 of this title, relating to Excavator Notice to Notification Center, an excavator shall mark, if applicable according to §18.3(c), the specific excavation area using white paint flags, or stakes, whichever is most visible for the terrain.

(b) An excavator shall mark the area of excavation using intervals that show the direction of the excavation.

§18.8. Operator Marking Requirements.

(a) A locator shall use all information necessary to mark underground pipelines accurately.

(b) Locators shall mark the approximate center line of an underground pipeline.

(c) If, in the process of marking an underground pipeline, a locator discovers a customer-owned underground pipeline, the locator shall make a reasonable effort to advise the excavator of the presence of the customer-owned underground pipeline.

(d) Where a proposed excavation crosses an underground pipeline, markings shall be at intervals that clearly define the route of the underground pipeline, to the extent possible.

(e) A locator shall mark underground pipelines by means of stakes, paint, flags, or a combination of two or more of these. The terrain, site conditions, and type and extent of the proposed excavation shall be considered in determining the most suitable means for marking underground pipelines.

(f) A locator shall mark at sufficient intervals to indicate clearly the approximate horizontal location and direction of the underground pipeline or pipelines. The distance between any two marks indicating the same line shall not exceed 20 feet; however, a shorter distance between marks may be necessary because of site conditions or directional changes of the underground pipeline.

(g) Markings of an underground pipeline greater than six inches in nominal outside dimension shall include the size in inches at every other mark.

(h) A locator shall extend all markings, if practical, at least one additional mark beyond the boundaries of the specific location of the proposed work as detailed on the line locate ticket.

(i) A locator shall make paint marks approximately eight to ten inches in length and one to two inches in width except when spot marking is necessary. A locator shall make a minimum of three separate marks for each underground pipeline marking.

§18.9. Options for Managing an Excavation Site in the Vicinity of an Underground Pipeline.

(a) After complying with the notice requirements of §18.3 of this title, relating to Excavator Notice to Notification Center, an excavator and an operator may jointly establish the protocols applicable to an excavation site in the vicinity of underground pipelines based on the particular characteristics of each job. The protocols applicable to an excavation site may:

(1) designate the contact person or persons for each entity working at an excavation site;

(2) establish the required mode or modes of communication among all entities working at an excavation site, e.g., telephone or other electronic means or face-to-face meetings at prescribed times or intervals;

(3) provide the method for coordinating work activities among all entities working at an excavation site;

(4) provide for the ownership and/or possession of the locate ticket or tickets;

(5) declare which entity or entities must have the locate ticket or locate ticket number before beginning work;

(6) state the life of a locate ticket and the circumstances that require refreshing the locate ticket;

(7) state the schedule of work on the excavation and, if applicable, the chronological order in which applicable locate tickets are to be located;

(8) designate the extent of the tolerance zone, provided that it shall not be less than half the nominal diameter of the underground pipeline plus a minimum of 18 inches on either side of the outside edge of the underground pipeline on a horizontal plane and the type of excavation permitted within the tolerance zone; and

(9) provide for any other agreement with respect to excavation activities and/or marking requirements that will or will tend to ensure the proper and safe excavation in the vicinity of an underground pipeline.

(b) If an excavator and an operator jointly establish protocols pursuant to this section, both the excavator and the operator shall make and retain a record of the agreement.

§18.10. Excavation within Tolerance Zone.

(a) An excavator shall comply with the requirements of Texas Health & Safety Code, Subchapter H, relating to Construction Affecting Pipeline Easements and Rights-of-Way.

(b) When excavation is to take place within the specified tolerance zone, an excavator shall exercise such reasonable care as may be necessary to prevent damage to any underground pipeline in or near the excavation area. Methods to consider, based on certain climate or geographical conditions, include hand digging when practical, soft digging, vacuum excavation methods, pneumatic hand tools. Other mechanical methods or other technical methods that may be developed may be used with the approval of the underground pipeline operator. Hand digging and non-invasive methods are not required for pavement removal.

§18.11. Reporting Requirements.

(a) Each operator of an underground pipeline shall report to the Commission all damage to its pipelines caused by an excavator. Within 10 days of the damage incident or of the operator's actual knowledge of the damage incident, an operator shall submit the information to the Commission through TDRF, which may be accessed at http://www.rrc.state.tx.us/formpr/index.html using its assigned operator identification code.

(b) Each excavator that damages an underground pipeline shall notify the operator of the damage through the notification center immediately but not later than two hours following the damage incident. The excavator shall also submit report of the damage incident to the Commission using TDRF, which may be accessed at http://www.rrc.state.tx.us/formpr/index.html and the excavator sign-in, within 10 days of the incident.

(c) Each excavator that makes an additional call to the notification center pursuant to §18.4(e) of this title, relating to Excavator Obligation to Avoid Damage to Underground Pipelines, because the excavator did not receive a positive response, shall report that fact to the Commission through TDRF. An excavator shall also report an operator's failure to provide a positive response to a second call to the Commission through TDRF.

(d) An emergency response official, a member of the general public, or another person aware of damage to an underground pipeline is encouraged to submit an incident form using TDRF, which can be ac-

cessed at http://www.rrc.state.tx.us/formpr/index.html. Entries can be made through the general public or emergency response official sign-in.

§18.12. Penalty Guidelines.

(a) The penalty amounts shown in the table in this section are provided solely as guidelines to be considered by the Commission in determining the amount of administrative penalties for violations of the requirements of this chapter. The establishment of these penalty guidelines shall in no way limit the Commission's authority and discretion to assess administrative penalties in any amount up to the statutory maximum when warranted by the facts in any case.

(b) The amount of any penalty requested, recommended, or finally assessed in an enforcement action will be determined on an individual case-by-case basis for each violation, taking into consideration the following factors:

(1) the person's history of previous violations or formal warnings, including the number of previous violations or formal warnings;

(2) the seriousness of the violation and of any pollution resulting from the violation;

(3) any hazard to the health or safety of the public;

(4) the degree of culpability;

(5) the demonstrated good faith of the person charged; and

(6) any other factor the Commission considers relevant, including but not limited to the number of locate requests received and responded to by an operator and the number of location notifications given by an excavator in the previous year.

(c) The recommended monetary penalty for a violation may be reduced by up to 50% if the person charged agrees to a settlement before the Commission conducts an administrative hearing to prosecute a violation. Once the hearing is convened, the opportunity for the person charged to reduce the basic monetary penalty is no longer available. The reduction applies to the basic monetary penalty amount requested and not to any requested enhancements.

(d) In determining the total amount of any monetary penalty requested, recommended, or finally assessed in an enforcement action, the Commission may consider, on an individual case-by-case basis for each violation, the demonstrated good faith of the person charged. Demonstrated good faith includes but is not limited to actions taken by the person charged before the filing of an enforcement action to remedy, in whole or in part, a violation of the rules in this chapter or to mitigate the consequences of a violation of the rules in this chapter.

(e) Depending upon the nature of and the consequences resulting from a violation of this chapter, the Commission may impose a non-monetary penalty, such as requiring attendance at a safety training course, or may issue a warning.
Figure: 16 TAC §18.12(e)

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on June 1, 2007.

TRD-200702133

Mary Ross McDonald
Managing Director
Railroad Commission of Texas
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Proposal publication date: December 22, 2006
For further information, please call: (512) 475-1295

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PART 2. PUBLIC UTILITY COMMISSION OF TEXAS

CHAPTER 26. SUBSTANTIVE RULES APPLICABLE TO TELECOMMUNICATIONS SERVICE PROVIDERS

SUBCHAPTER J. COSTS, RATES AND TARIFFS

16 TAC §26.223

The Public Utility Commission of Texas (commission) adopts amendments to §26.223, relating to the Prohibition of Excessive COA/SPCOA Usage Sensitive Intrastate Switched Access Rates with changes to the proposed text as published in the February 9, 2007, issue of the *Texas Register* (32 TexReg 494). The amendments are necessary to harmonize the impact of changes in incumbent local exchange carrier (ILEC) access charges mandated by Chapter 65 of the Public Utility Regulatory Act (PURA) with the commission's re-calculation of the weighted statewide average composite usage sensitive intrastate switched access rates as required under §26.223. Chapter 65 requires that the large ILECs that have chosen to transition to deregulation substantially reduce their minute of use rates (in the aggregate) associated with intrastate switched access each year for three successive years. Under PURA §65.202, a transitioning ILEC is required to reduce its intrastate switched access rates by approximately one third of the difference between the switched access rates it charges for intrastate minutes of use and interstate minutes of use. Such ILEC is required to make such reductions each year on July 1, beginning on July 1, 2006. Harmonizing PURA Chapter 65 with §26.223 will ultimately prohibit a competitive carrier that chooses to adopt these statewide average composite switched access rates from charging excessive usage sensitive switched access rates.

The amendments to §26.223 will require an annual, instead of a biennial, re-calculation of weighted statewide average composite usage sensitive intrastate switched access rates until June 2010, and a biennial re-calculation thereafter. The amendments will also change the timeline for completion of the task of developing new statewide average rates, will establish new dates for submission of certificate of convenience and necessity (CCN) holder access charge information necessary to calculate the rates, and will establish new due dates for industry compliance submissions associated with the re-calculation of the statewide average composite usage sensitive switched access rates. Additionally, unnecessary or outdated sections related to the initial implementation of this rule have been deleted. The amendments to §26.223 provided herein are adopted under Project Number 33060.

The commission received written comments on its proposals for amendments from Southwestern Bell Telephone, L.P. d/b/a

AT&T Texas (AT&T Texas) on March 12, 2007. No other comments or replies to comments were received by the commission.

AT&T Texas fully supports the amendments to §26.223. AT&T Texas offered two minor modifications for clarification purposes only.

§26.223(e)(1)(E)

Subsection (e)(1)(E) delineates the conversion of revenues from monthly rate elements to minute of use (MOU) rates. Regarding the submission of MOU information, AT&T Texas recommends that the word "local" be inserted in front of the words "switching MOUs" in the first sentence of this subsection such that it would read as follows:

Additional revenues submitted under subsection (g)(8) for monthly rate elements associated with switched access shall be converted to MOU rates using the local switching MOUs provided by the CCN holder.

AT&T Texas indicates that the addition is necessary in order to make clear that the process will utilize the local switching MOUs as opposed to the tandem switching MOUs.

Commission response

The commission believes that AT&T Texas's clarification is consistent with the current practice used by staff in the development of the statewide average rates. Therefore, the commission agrees that the minor clarification is appropriate and adopts AT&T Texas's suggestion.

§26.223(g)(7)

Subsection (g)(7) addresses the total actual originating and terminating MOU data that ILECs are required to provide to the commission for the re-calculation of the statewide average rates, AT&T Texas recommends that the words "that is billed on an MOU basis" be added at the end of this subsection so that it would read as follows:

The total actual originating and terminating MOU for the most recent 12-month period (August 1 through July 31) for each rate element in paragraphs (1) - (6) of this subsection that is billed on an MOU basis.

AT&T Texas indicates that the additional wording is necessary because some of the rate elements listed in paragraphs 1 through 6 are not billed by AT&T Texas on an MOU basis (*i.e.*, those elements billed on a monthly, non-usage sensitive basis). AT&T Texas further indicates that for those rate elements that are billed on a monthly, non-usage sensitive basis, AT&T Texas and other ILECs will be providing revenue data and units pursuant to the process outlined in subsection (g)(8).

Commission response

The commission believes that AT&T Texas's clarification is consistent with the current practice used by staff in the development of the statewide average rates for switched access. Therefore, the commission agrees that the minor clarification is appropriate and adopts AT&T Texas's suggestion.

In adopting these sections, the commission makes other minor, non-substantive modifications for the purpose of clarifying its intent.

This amendment is adopted under the Public Utility Regulatory Act, Texas Utilities Code Annotated §14.002 and §14.052, and specifically, PURA §52.155 which grant(s) the commission all jurisdiction necessary to enforce the prohibition of excessive access charges and PURA Chapter 65, Subchapter E, that relates to the reduction of switched access rates by transitioning companies.

Cross Reference to Statutes: Public Utility Regulatory Act §§14.002, 15.052, 52.155, and 65.201 - 65.203.

§26.223. Prohibition of Excessive COA/SPCOA Usage Sensitive Intrastate Switched Access Rates.

(a) Purpose. The purpose of this section is to implement Public Utility Regulatory Act (PURA) §52.155, which addresses the usage sensitive intrastate switched access rates that can be charged by a telecommunications utility that holds a certificate of operating authority (COA) or a service provider certificate of operating authority (SPCOA) (COA/SPCOA).

(b) Applicability. This section applies to usage sensitive intrastate switched access rates of COA/SPCOA holders, including but not limited to, originating and terminating carrier common line (CCL), originating and terminating local switching (LS), originating and terminating switched transport (TR), originating and terminating tandem switching (TS), and originating and terminating tandem switched transport (TST).

(c) Requirements for COA/SPCOA usage sensitive intrastate switched access rates. A telecommunications utility that holds a COA or a SPCOA may not charge a higher aggregate amount, including any rate elements not charged by the holder of the certificate of convenience and necessity (CCN), for originating or terminating usage sensitive intrastate switched access than the prevailing rates charged by the CCN holder or the holder of a COA issued under Chapter 65 in whose territory the call originated or terminated unless:

(1) the commission specifically approves the higher rate; or

(2) subject to commission review, the telecommunications utility establishes statewide average composite originating and terminating usage sensitive intrastate switched access rates based on a reasonable approximation of traffic originating and terminating between all holders of certificates of convenience and necessity in this state.

(d) Governance of Switched Access Rates under PURA Chapter 65. Notwithstanding subsection (c), PURA Chapter 65 governs the switched access rates of a company that holds a COA issued under PURA Chapter 65.

(e) Statewide average composite rates. Weighted statewide average composite usage sensitive intrastate switched access rates will be developed based upon the submission of CCN holders' compliance filings pursuant to subsection (g) of this section.

(1) Methodology. The commission shall use the following information and methodology for development of the weighted statewide average composite usage sensitive intrastate switched access rates separately for each originating and for each terminating rate element category in subsection (g)(1) - (6) of this section:

(A) Each CCN holder's individual rate elements' rates will be multiplied by the total actual minutes of use (MOUs) for that rate element, producing a total revenue for each rate element for each CCN holder.

(B) Revenues for each CCN holder's rate element will be added to create a statewide total revenue for that rate element.

(C) The actual MOUs for each CCN holder's rate element will be added to create a statewide total actual MOUs for that rate element.

(D) The statewide total revenue for that rate element will be divided by the statewide total actual MOUs for that rate element, producing a weighted statewide average composite usage sensitive intrastate switched access rate for that switched access rate element.

(E) Additional revenues submitted under subsection (g)(8) of this section for monthly rate elements associated with switched access shall be converted to MOU rates using the local switching MOUs provided by the CCN holder. The converted MOU rates shall be used to revise the weighted statewide average composite usage sensitive intrastate switched access rates calculated pursuant to subparagraph (D) of this paragraph.

(2) Re-calculation.

(A) The commission shall re-calculate the weighted statewide average composite usage sensitive intrastate switched access rates annually until June, 2010 based upon the submissions of the CCN holders, as required in subsection (g) of this section. The commission shall endeavor to complete such re-calculation by November 15 of each year.

(B) Any certificated telecommunications utility may file a petition requesting that the commission re-calculate the weighted statewide average composite usage sensitive intrastate switched access rates at any time. The commission shall grant the petition for re-calculation if it concludes that the petition has provided just cause for re-calculation.

(C) As provided in subsection (g) of this section, the commission may also require compliance submissions by CCN holders for re-calculation of the weighted statewide average composite usage sensitive intrastate switched access rates as appropriate because of significant changes in usage sensitive intrastate switched access rates or in response to the request of affected parties, as specified in subparagraph (B) of this paragraph.

(D) After June 2010, the commission shall re-calculate the weighted statewide average composite usage sensitive intrastate switched access rates biennially. The commission shall endeavor to complete such re-calculation by November 15.

(f) Approval of higher rates.

(1) A COA/SPCOA holder seeking approval of originating and/or terminating usage sensitive intrastate switched access rates that in the aggregate, including any rate elements not charged by the CCN holder, are higher than the aggregate of the originating and/or terminating usage sensitive switched access rate elements charged by the CCN holder in the COA/SPCOA's territory may do so by filing an application with the commission subject to the procedures outlined in Procedural Rule §22.33 of this title (relating to Tariff Filings). The COA/SPCOA's application must provide, at a minimum, the following information:

(A) Cost justification for each rate element.

(B) Rationale for implementation of the higher rate for each rate element.

(2) A COA/SPCOA holder's application must address all of the applicable switched access rate elements in subsection (b) of this section.

(3) The commission shall publish notice of the application in the *Texas Register*.

(g) Requirement for CCN holders compliance submissions. Until June, 2010, all CCN holders must provide the following intrastate data to the commission as a compliance filing on an annual basis; and as of June, 2010 and thereafter on a biennial basis, by September 15:

(1) The current tariffed rate for originating and terminating CCL.

(2) The current tariffed rate for originating and terminating LS.

(3) The current tariffed rate for originating and terminating TR.

(4) The current tariffed rate for originating and terminating TS.

(5) The current average per minute rate for originating and terminating TST.

(6) The current originating and terminating tariffed rate(s) for any other usage sensitive intrastate switched access rate element(s).

(7) The total actual originating and terminating MOUs for the most recent 12-month period (August 1 through July 31) for each rate element in paragraphs (1) - (6) of this subsection that is billed on an MOU basis.

(8) The total revenues for the most recent 12-month period (August 1 through July 31) received from any switched access monthly rate element used to transport or switch the access traffic listed in paragraphs (1) - (6) of this subsection that may be specifically attributable to the element identified (*e.g.*, local switching, transport).

(h) Requirements of COA/SPCOA holders compliance submissions.

(1) No later than 20 days after the effective date of the commission order re-calculating the weighted statewide average composite usage sensitive switched access rates, COA/SPCOA holders shall:

(A) file an application under subsection (f) of this section; or

(B) file compliance tariffs/price lists to be effective 10 days from the filing date of the compliance tariffs/price lists containing originating and terminating usage sensitive intrastate switched access rates that do not exceed the prevailing rates charged by the CCN holder in each territory in which the COA/SPCOA holder operates; or

(C) file compliance tariffs/price sheets with originating and terminating usage sensitive intrastate switched access rates that do not exceed the re-calculated weighted statewide average composite usage sensitive switched access rates established by the commission to be effective 10 days from the filing date of the compliance tariffs/price sheets; or

(D) file a letter with the commission demonstrating that no rate revisions are necessary in order to comply with this section.

(2) If a COA/SPCOA holder establishes usage sensitive intrastate switched access rates pursuant to paragraph (1)(B) of this subsection and the underlying CCN holder(s) whose rates were the basis for the COA/SPCOA holder's usage sensitive intrastate switched access rates are modified, no later than 20 days after said CCN holder's rates are modified, the COA/SPCOA holder shall:

(A) file an application under subsection (f) of this section; or

(B) file compliance tariffs/price lists to be effective 10 days from the filing date of the compliance tariffs/price lists containing originating and terminating usage sensitive intrastate switched access rates that do not exceed the prevailing rates charged by the CCN holder in each territory in which the COA/SPCOA holder operates; or

(C) file compliance tariffs/price sheets with originating and terminating usage sensitive intrastate switched access rates that do

not exceed the most recent commission established weighted statewide average composite usage sensitive switched access rates established by the commission to be effective 10 days from the filing date of the compliance tariffs/price sheets; or

(D) file a letter with the commission demonstrating that no rate revisions are necessary in order to comply with this section.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on May 31, 2007.

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Adriana A. Gonzales
Rules Coordinator
Public Utility Commission of Texas
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Proposal publication date: February 9, 2007
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TITLE 19. EDUCATION

PART 8. WINDHAM SCHOOL DISTRICT

CHAPTER 300. GENERAL PROVISIONS

19 TAC §300.3

The Windham School District Board of Trustees adopts new rule, Title 19, Part 8, Chapter 300, General Provisions, §300.3, Employment Referral Services for Offenders, which authorizes the District to adopt a memorandum of understanding (MOU) between the Texas Department of Criminal Justice (TDCJ), the Texas Workforce Commission (TWC), the Texas Youth Commission (TYC) and the Windham School District (WSD). The new rule is adopted with a minor change to the text as published in the April 13, 2007, issue of the *Texas Register* (32 TexReg 2089).

The purpose of the rule is to establish the responsibilities of each agency in the administration of the Project for Reintegration of Offenders (Project RIO).

No comments were received.

The new rule is adopted under Texas Government Code, §501.095 and Texas Labor Code, §306.004 and §306.005.

Cross Reference to Statutes: Texas Education Code, §19.011 and Texas Government Code §771.001, et seq.

This District hereby certifies that the adoption has been reviewed by legal counsel and was found to be a valid exercise of the District's legal authority.

§300.3. Employment Referral Services for Offenders--Memorandum of Understanding.

(a) The Windham School District (WSD) Board of Trustees adopts the following memorandum of understanding (MOU) with the Texas Workforce Commission, the Texas Youth Commission (TYC) and the Texas Department of Criminal Justice (TDCJ).
Figure: 19 TAC §300.3(a)

(b) This MOU is required by the Texas Government Code, §501.095 and Texas Labor Code, §306.004 and §306.005.

(c) Copies of the MOU are filed in the WSD Administration Building, 804 F.M. 2821 West, Huntsville, Texas 77320 and may be reviewed during regular business hours.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on May 25, 2007.

TRD-200702085
Melinda Hoyle Bozarth
General Counsel, Texas Department of Criminal Justice
Windham School District
Effective date: June 14, 2007
Proposal publication date: April 13, 2007
For further information, please call: (512) 463-0422

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TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 133. HOSPITAL LICENSING

The Executive Commissioner of the Health and Human Services Commission (commission) on behalf of the Department of State Health Services (department) adopts the repeal of §§133.1, 133.2, 133.21 - 133.26, 133.41 - 133.48, 133.61, 133.62, 133.81, 133.101, 133.102, 133.121, 133.122, 133.141 - 133.143, 133.161 - 133.169, and new §§133.1, 133.2, 133.21 - 133.26, 133.41 - 133.48, 133.61, 133.62, 133.81, 133.101, 133.102, 133.121, 133.141 - 133.143, 133.161 - 133.169, concerning the regulation of hospitals. The new §§133.2, 133.21, 133.23, 133.26, 133.41, 133.42, 133.45, 133.162, 133.163, 133.166 and 133.167 are adopted with changes to the proposed text as published in the December 15, 2006, issue of the *Texas Register* (31 TexReg 9961). The repeal of §§133.1, 133.2, 133.21 - 133.26, 133.41 - 133.48, 133.61, 133.62, 133.81, 133.101, 133.102, 133.121, 133.122, 133.141 - 133.143, 133.161 - 133.169 and new §§133.1, 133.22, 133.24, 133.25, 133.43, 133.44, 133.46 - 133.48, 133.61, 133.62, 133.81, 133.101, 133.102, 133.121, 133.141 - 133.143, 133.161, 133.164, 133.165, 133.168, and 133.169 are adopted without changes and, therefore, the sections will not be republished.

BACKGROUND AND PURPOSE

The repeals and new sections are necessary to update, reorganize and clarify the rules and to implement legislation by the 79th Legislature, Regular Session, 2005, specifically, the amendments to Health and Safety Code (HSC), Chapter 161, Subchapter T (Senate Bill (SB) 316) relating to information provided to parents of newborn children; Occupations Code, §164.052 (SB 419) relating to parental consent for abortion; Occupations Code, §162.052 (SB 872) relating to certain disclosure requirements regarding niche hospitals; HSC, §161.0052 (SB 1330) relating to the immunization of elderly persons; HSC, Chapter 256 (SB 1525) relating to safe patient handling and movement practices of nurses in hospitals; HSC, Chapter 322 (House Bill (HB) 677) relating to emergency services for sexual assault survivors; Occupations Code, §301.353 (HB 1718) relating to the regulation of certain nursing practices, including circulating duties in an operating room; HSC, §241.023 (HB

2471) relating to the issuance of a single license for multiple hospitals; and HSC, §241.022 (HB 3357) relating to information required on a hospital license application.

Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 133.1 - 133.2, 133.21 - 133.26, 133.41 - 133.48, 133.61 - 133.62, 133.81, 133.101 - 133.102, 133.121, 133.122, 133.141 - 133.143, and 133.161 - 133.169 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

Proposed new §§133.1, 133.2, 133.21 - 133.26, 133.41 - 133.48, 133.61, 133.62, 133.81, 133.101, 133.102, 133.121, 133.141 - 133.143, and 133.161 - 133.169 provide clarification to the rules, update references to statutes and rules, and change the name of the department and its programs. The new §133.2 adds definitions and deletes definitions not used in the rules and those that were moved to a specific section when the use was confined to that section. The new §133.21 sets out conditions under which multiple hospital locations may be licensed under one license number. New §133.22 and §133.23 include a proposal to collect additional ownership information on hospital license applications. The new §133.41 requires all hospitals to document all approvals or delegations of anesthesia services and include the training, experience, and qualifications of the person who provided the service; to have an emergency department with staff on duty and available to initiate immediate appropriate lifesaving measures; to participate in the local emergency medical service system; to develop, implement and enforce policies relating to survivors of sexual assault, workplace safety, and safe patient handling and movement practices by nurses in hospitals; to require a registered nurse be on duty in each licensed hospital location at all times; to comply with certain requirements for renal dialysis services; and to require direct supervision by a qualified registered nurse circulator of licensed vocational nurses and surgical technologists assisting in circulatory duties in the operating room. The new §133.45 requires hospitals to develop, implement and enforce policies (1) to implement an all-hazard disaster preparedness plan; (2) to ensure that parents of newborn children receive information concerning postpartum depression and other emotional trauma associated with pregnancy and parenting, including the prevention of shaken baby syndrome, immunizations, and newborn screening; (3) to ensure compliance with statutory provisions relating to abortion and informed consent and parental consent for abortion; and (4) to provide influenza and pneumococcal vaccines for elderly persons. The repeal of §133.62 deletes procedural language for submission and approval of cooperative agreements deemed unnecessary because it is duplicative of statutory language. New §133.62 indicates current information regarding cooperative agreements.

New §§133.141 - 133.143 and 133.161 - 133.165 change the requirement for compliance with the National Fire Protection Association's (NFPA) Life Safety Code (LSC) from the 2000 edition to the 2003 edition, and provide new edition dates and section numbers for NFPA and other standards referenced in the sections. New §133.143 establishes conditions for the use of alcohol-based products when used for surgical skin preparation; new §133.162 clarifies prohibitions relating to hospital construction in designated 100-year flood plains, and requires a hospital to consider the provisions of HSC Chapter 256 relating to safe patient handling and movement practices; new §133.163 clarifies spatial requirements for patient multiple-bed rooms, establishes signage specifications for the emergency entrance to a hospital, and sets out standards for a decontamination room, intermediate care suite, and universal care suite when hospitals provide the services; new §133.165 clarifies that all spaces in a hospital must be contiguous when the building is shared with other hospitals or non-hospital occupancies, and clarifies the services and facilities that must be provided directly by the hospital and those that may be shared; and new §133.166 clarifies requirements for mobile, relocatable and transportable units when the units are permanently attached to a hospital. New §133.169 updates existing tables and provides two new tables for clarity of requirements relating to the nurses calling systems and multiple-bed room configurations.

The department, on behalf of the commission, has reviewed and prepared a response to the comments received regarding the proposed rules during the comment period, which the commission has reviewed and accepts. The commenters were individuals, associations, and/or groups, including the following: Baylor Medical Center at Trophy Club, Baylor Specialty Health Centers, Children's Memorial Hermann Hospital, CHRISTUS Health Care, CHRISTUS Santa Rosa Health Care, Coalition for Nurses in Advanced Practice, Cook Children's Health Care System, El Paso County Hospital District (R. E. Thomason General Hospital), Greater Houston Anesthesiology, P.A., HillCo Partners, Mary Shiels Hospital, Medical Multiplex, Inc., National Surgical Hospitals, North Hills Hospital, PageSoutherlandPage Architects, Seton Family of Hospitals, Smith Seckman Reid, Inc., Sterling Barnett Little, Inc., Sugar Land Surgical Hospital, Sweeny Hospital, Texas Association of Nurse Anesthetists, Inc., Texas Commission on Environmental Quality, Texas Hospital Association (THA), Texas Nurses Association, Texas Organization of Rural and Community Hospitals (TORCH), Texas Society of Anesthesiologists, Texas Society of Health-System Pharmacists, Texas State Board of Pharmacy, The Methodist Hospital System, The Physicians Centre, Travis County Healthcare District, University Health System. The commenters were not against the rules in their entirety; however, the commenters suggested recommendations for changes as discussed in the summary of comments.

Comment: Concerning §133.2(3), a commenter supports the rules, but recommended modifying the definition of "advanced practice nurse (APN)" to include advanced practice nurses who are not licensed in Texas but holds a license in another state party to the Nurse Licensure Compact. This would bring the definition of "advanced practice nurse (APN)" into conformity with the definition of "registered nurse (RN)" proposed in these rules. The commenter suggested removing the portion of the definition that refers to the educational grounds upon which the Board of Nurse Examiners for the State of Texas (BNE) authorizes APNs, as that seems unnecessary for this definition. The commenter also suggested changing the word "approved" to "authorized" to describe the action taken by the BNE, and changing the word "and" to "or" in the list of the types of nurses.

Response: The commission agrees with the commenter and has made the recommended changes.

Comment: Concerning §133.2(40), a commenter recommended that, in this section, the word "inpatient" be changed to the word "patient". The definition of "premises" relates only to inpatient facilities. Hospitals serve many outpatients in various capacities, but many older, smaller facilities have been unable to build

outpatient facilities such as outpatient therapy facilities, certain types of imaging, and other outpatient treatment areas within the hospital inpatient building. The definition is too restrictive.

Response: The commission disagrees with the commenter. The rule at §133.21(c)(2) states that a hospital license shall not include off-site outpatient facilities. A hospital may provide outpatient services that are not included in the hospital license. The definition of premises is statutory language describing that the department may issue a license only for the premises of a hospital and person or governmental unit named in the application, and the department may issue one license for multiple hospitals if all the requirements in the definition are met. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.21(c)(2), a commenter requested that "off-site" be changed to "off-premises". This is similar in substance to the comment on "premises". "Off-site" has never been defined, but it is presumed by surveyors to mean "off-premises." Because small hospitals may not have enough space in the hospital, an outpatient facility, such as an outpatient therapy center, may be, by necessity, located across the street. Several member hospitals have been required by surveyors to relocate outpatient services (particularly outpatient physical therapy services) into the inpatient hospital, at great expense.

Response: The commission disagrees with the commenter. A hospital may provide outpatient services that are not included in the hospital license. The rules at §133.163(v) describe the architectural requirements for an outpatient suite. Outpatient services that the hospital provides to patients under the hospital license shall be within the hospital. If the outpatient suite is located in an office building or other building, that portion shall be physically connected to the hospital and become contiguous to the hospital. In no case may one leave the hospital, traverse the other occupancies, and then reenter the hospital to access the remaining portion of the hospital. To insure these rules are enforced correctly, all staff were notified on June 1, 2006 that the patient quality care unit manager must be contacted to participate in the enforcement, if a hospital is required to relocate a department. The department, THA and TORCH have jointly developed instructions on outpatient facilities. When finalized these instructions will be distributed to all licensed hospitals. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.21(c)(5), two commenters requested deletion as some hospitals currently have a free standing ambulatory surgical center (ASC) on their campus; other hospitals are considering such an arrangement. From a patient safety standpoint, placement of a hospital's ASC on the hospital's campus or premises ensures a more rapid and safer transfer of an ASC patient who may develop complications and require hospitalization. In addition, prohibiting placement of a hospital and its freestanding ASC on the same premises or campus likely will limit a hospital's ability to compete with other ASC owners in the hospital's service area.

Response: The commission disagrees with the commenters that the rule should be deleted. "Premises" is defined in the rules. The rule does not prohibit a licensed ASC being placed on a hospital's campus. The rule does prohibit any part of the campus being dually licensed as a hospital and as an ambulatory surgical center. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.26(f), a commenter recommended that the amount of the subscription and convenience fees be clarified and that a statement be added that the fee is in addition to the license fee at each renewal application. It is unclear as to how much these fees will add to the amounts paid and whether hospitals will be required to use TexasOnline.

Response: The commission agrees with the commenter and has added that at each renewal application, in addition to the license fee, there shall be a $20 TexasOnline subscription fee. The use of TexasOnline is optional, and hospitals are not required to use it.

Comment: Concerning §133.41(a)(1), a commenter recommended the deletion of the word "qualified" as it is unclear from the context whether "qualified' is defined by the text that follows, "who have been approved by the facility to provide anesthesia services" or may be defined elsewhere in the Texas Administrative Code.

Response: The commission agrees with the commenter and has deleted the word "qualified".

Comment: Concerning §133.41(a), a commenter supported the proposed anesthesia changes, especially the deletion of the wording in the current §133.41(a)(1)(D). The commenter commended the recognition that it is the department's responsibility to regulate hospitals and the responsibility of the respective licensing boards to regulate the health care professionals working in hospitals. The commenter recommended adding "licensed" to describe personnel in §133.41(a)(1), as it is not clear if every anesthesia provider is to be authorized by law.

Response: The commission disagrees with the commenter. The Texas Medical Board regulates medical practice. The Medical Practice Act does give physicians the authority to delegate certain medical acts. This includes delegation of the administration of anesthesia to anesthesiologist assistants. Anesthesiologist assistants are not licensed in the state of Texas. This addition would regulate medical practice by limiting the ability of a physician to appropriately delegate the administration of anesthesia. The commission does regulate licensed hospitals, but does not regulate medical practice. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(a)(2)(C), a commenter stated that requiring an evaluation of patient color is ambiguous. It is not clear if the evaluation is to measure perfusion or oxygen saturation, or to record the racial color of the patient.

Response: The commission agrees with the commenter and has changed "patient color" to "patient's oxygen saturation level".

Comment: Concerning §133.41(c)(5)(C), (e)(1)(A), (n)(2), and (u)(3), a commenter recommended clarifying that the director is a medical director or clinical director who is a physician. Since physicians are normally not employed by the hospital, a hospital staff member has usually been designated as the administrative director. Because this wording indicates that only a physician may be designated as a director, the surveyors have required that the hospital staff be re-designated with another title.

Response: The commission agrees with the commenter and has clarified that the director shall be a medical director or a clinical director who is a physician.

Comment: Concerning §133.41(d)(2)(E)(vi), a commenter questioned the necessity of maintaining a four-day, rather than a three-day, supply of food.

Response: At §133.163(e)(1)(B)(iii), the current and proposed rules require the facility to provide storage of food for emergency use for a minimum of four calendar days. The requirement to ensure there is a four-day food supply on hand at all times, was added to the proposed rules at §133.41(d)(2)(E)(vi) for clarity. During one of the stakeholder meetings, the number of days was discussed. However, this meeting was held after hurricane Rita. Based on the lessons learned during the hurricane, it was decided to maintain the requirement of a four-day supply of food. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e), a commenter supported the requirement that all hospital locations have an emergency suite.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e)(2)(C)(i), a commenter stated that per this legislation, all have to have at least one full time board certified emergency room physician 24/7. So, some hospitals may have emergency room doctors who are not board certified, and they are going to be looking for a physician on each shift to meet this requirement. They estimated that the cost to their hospital would be $1,000,000.

Response: The commission disagrees with the commenter. The proposed rule does not require all hospitals to have at least one full time board certified emergency room physician on duty in the emergency treatment area at all times. The proposed rule does require general hospitals, except for comprehensive medical rehabilitation hospitals and pediatric and adolescent hospitals that generally provide care that is not administered for or in expectation of compensation, located in counties with a population of 100,000 or more to have a physician qualified to provide emergency medical care on duty in the emergency treatment area at all times. The governing body is responsible for the appointment of the medical staff and to determine, in accordance with state law and with the advice of the medical staff, which categories of practitioners are eligible candidates for appointment to the medical staff. The medical staff bylaws must describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e)(2)(C)(i), three commenters recommended all general hospitals in Texas be required to have a licensed health care provider trained in emergency medical care on duty in the facility at all times. A licensed health care provider, in this case, includes an emergency nurse practitioner (ENP). ENPs are already used throughout the state to provide emergency and urgent health care services to individuals of all ages. These advanced practice nurses' training focuses on the management of acute illnesses, trauma, and/or chronic unstable illnesses requiring immediate attention, stabilizing the individual's condition, and determining appropriate referral and follow-up care. ENPs in Texas currently provide care in ambulatory, urgent care, and emergency department settings. No general hospitals in Texas should be excluded. All citizens of Texas deserve access to facilities that provide this level of emergency services. Emergency care should not be confused with trauma care staffing.

Response: The commission disagrees with the commenters. The rules at §133.41(e)(2)(A) require that there shall be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the hospital. Except for comprehensive medical rehabilitation hospitals and pediatric and adolescent hospitals that generally provide care that is not administered for or in expectation of compensation, there shall be on duty and available at all times at least one person qualified as determined by the medical staff to initiate immediate appropriate lifesaving measures. The commission acknowledges the value of mid-level practitioners, including physician assistants (PAs) and advanced practice nurses (APNs), for patients with a variety of medical problems, and appreciates that non-physician providers can enhance the ability of both rural and urban health care facilities to provide a broader range of patient care services to their population base. The physical presence of PAs and APNs in general hospitals in Texas counties with a population greater than 100,000 does not meet the essential criterion that requires the physical presence of on-duty physicians to care for patients with critical medical or surgical conditions. General hospitals in counties with a population greater than 100,000 that elect to utilize PAs and APNs in their facilities must ensure that the scope of practice of these mid-level practitioners is clearly delineated and consistent with state regulations. This delineation should include the types of patients with critical medical or surgical conditions that require referral to the on-duty physician qualified to provide emergency medical care. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e)(2)(C)(i) and (ii), two commenters recommended exempting hospitals designated as critical access hospitals (CAHs) by the Centers for Medicare & Medicaid Services (CMS) from the requirement to have a physician qualified to provide emergency medical care on duty in the emergency treatment area at all times. This requirement would be cost prohibitive for a very limited number of cases. The commenters recommended requiring CAHs to be required to have a physician on-call and able to respond in person, or by radio or telephone within 30 minutes.

Response: The commission agrees with the commenters and has made the recommended changes.

Comment: Concerning §133.41(e)(2)(C)(i) and (ii), a commenter urged the withdrawal of the proposed rule and study of the issue in greater detail before placing the additional requirement on all hospitals in the state because the proposed rule is arbitrary and capricious in that it does not provide a tangible benefit; the proposed rule will raise the costs of providing emergency care services statewide and unnecessarily wastes hospital resources; and the proposed rule exceeds the rulemaking authority granted under HSC §214.026.

Response: The commission disagrees with the commenter. The current rule at §133.41(e)(1)(B)(iii) requires the hospital to provide that one or more physicians shall be available at all times for emergencies. The proposed rule clarifies that in larger counties, the available physician must be an on-duty physician. The proposed rule is not arbitrary or capricious because it will provide a tangible benefit to the people of Texas by requiring immediate access to a physician in emergency rooms located in larger counties, further serving and protecting the health needs of Texans. The new rule clearly is within the scope of statutory authority. HSC §241.026 requires adoption and enforcement of rules to further the purpose of this chapter. HSC §241.002 states the purpose of this chapter is to protect and promote the public health and welfare by providing for the development, estab-

lishment, and enforcement of certain standards in the construction, maintenance, and operation of hospitals. HSC §241.026 requires the rules at a minimum to address minimum requirements for staffing by physicians and nurses. The new rule was proposed by a large group of stakeholders who also considered the Medicare conditions of participation (CoPs) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards when proposing the rule. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e)(5), a commenter agreed with the requirement that all emergency departments participate in their local emergency medical service (EMS) system.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e)(6), a commenter supported the requirement that all emergency departments ensure the provision of emergency services for survivors of sexual assault.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e)(6)(A)(ii), a commenter recommended that the term "community-wide" be amended to read "community-wide or regional" plan. "Community-wide" is not defined, and many small and rural hospitals are the only health care provider in the community, as that term is commonly used. The requirements of this section are beyond the capability of many small hospitals.

Response: The commission agrees with the commenter that the definition of "community-wide plan" is not in the proposed rules, has added the statutory definition from Health and Safety Code, Chapter 322, to the definitions in the rules, and renumbered the definitions.

Comment: Concerning §133.41(f)(4)(C)(i)(II), a commenter agreed that physicians should have the ability to require hospitals to participate in mediation.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(f)(4)(C)(i)(IV), a commenter appreciated the inclusion of the provision that allows hospital to require the provision of documentation of current clinical competency and professional training and experience.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(j)(1), a commenter recommended that the term "employ" be revised to read "employ or contract with" adequate personnel. Many medical records functions are often provided by independent contractors.

Response: The commission agrees with the commenter and has made the recommended change.

Comment: Concerning §133.41(j)(6), a commenter requested a definition of "as soon as possible".

Response: The commission has added, "As soon as possible would be the next time the prescriber or another practitioner who is responsible for the care of the patient and has been credentialed by the medical staff and granted privileges which are consistent with the written orders provides care to the patient, assesses the patient, or documents information in the patient's medical record."

Comment: Concerning §133.41(j)(7), two commenters requested that the proposed rule be revised to comply with the Medicare CoPs effective January 26, 2007.

Response: The commission agrees with the commenters and has deleted the phrase "promptly as specified by hospital policy" and has added "within 48 hours". This was the language in the March 2, 2006 proposed rules that the council recommended the Executive Commissioner's approval for publication in the *Texas Register*. As new issues arose, those rules were not published. During the review of that set of rules, stakeholders recommended the language be changed from "within 48 hours" to "promptly as specified by hospital policy" as there was no similar requirement in the CoPs at the time of the review. The Texas Hospital Licensing Law requires the consideration of the CoPs and the attempt to achieve consistency with those conditions. Most hospitals are Medicare certified and will be required to comply with the revised Medicare rule as there is no state law that designates a specific timeframe. Since the goal is to be as consistent as possible with the CoPs, this change has been made.

Comment: Concerning §133.41(j)(8)(C), two commenters agreed with the proposed language changing the history and physical exam requirement to be consistent with the JCAHO standards and the CMS regulations.

Response: The commission agrees with the commenters. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(k)(3)(F), a commenter stated that the change from seven days prior to admission to 30 days prior to admission will eliminate the conflict between state and federal regulations.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(n)(5)(B), a commenter requested clarification of this provision. It could be read as requiring retention of records for an indefinite period.

Response: The commission agrees with the commenter and has added "in accordance with §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material" for clarity. This is typically done when the facility requests termination of their radioactive material license.

Comment: Concerning §133.41(o)(2)(D), three commenters recommended revision as the term "location" is not defined, and it is unclear how this provision will be interpreted and applied by the department. Two of these commenters recommended a lesser requirement for CAHs. One of these commenters recommended CAHs have the same nurse staffing requirements as required by CMS under the CAH designation.

Response: The commission agrees with the commenters that the term "location" is not defined, and has added the phrase "building of a licensed hospital that contains at least one nursing unit where patients are present", and deleted the phrase "licensed hospital location at all times". The commission disagrees with the commenters that there should be a lesser requirement for CAHs as the rule has been clarified. The commission dis-

agrees with the commenter that CAHs should have the same nurse staffing requirements as required by CMS under the CAH designation. The federal rules allow a registered nurse, clinical nurse specialist, or licensed practical nurse be on duty whenever the CAH has one or more inpatients. Changing the requirement from a registered nurse to a licensed practical nurse would be a substantive change and would require public notice and comment.

Comment: Concerning §133.41(o)(2)(H)(i), a commenter requested the rule be amended to increase the minimum number of direct care nurses on the hospital nurse staffing advisory committee from one-third to one-half to enhance the effectiveness of the committee.

Response: The commission agrees with the commenter and has made the requested change.

Comment: Concerning §133.41(o)(3(B)(ii)), two commenters requested that the proposed rule be revised to comply with the Medicare Conditions of Participation (CoPs) effective January 26, 2007, and to be consistent with the language in §133.41(j)(7).

Response: The commission agrees with the commenters and has deleted the phrase "promptly as specified by hospital policy" and has added "within 48 hours".

Comment: Concerning §133.41(o)(4)(D), a commenter supports the rules, but suggested moving the reference to prescribing to §133.41(o)(4)(A) as it would be more logical. The commenter also suggested changing the phrase "administered under medical direction" to "in accordance with hospital policy", as "administered under medical direction" is not defined, and seems inappropriate since the phrase usually indicates that a physician must be present.

Response: The commission agrees with the commenter and has made the recommended changes.

Comment: Concerning §133.41(w)(1)(C), a commenter recommended that direct supervision be defined to mean that an RN is available to assist licensed vocational nurses (LVNs) and surgical technologists with duties. If direct means one-to-one supervision, it appears to duplicate efforts of the circulator.

Response: During one of the stakeholder meetings for these rule revisions, THA requested that the statutory language be used in these rules, as this was a highly negotiated law and the rules should not expand the language cited in the statute. THA's comments and the department response have been on the department web site since July 26, 2006. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.42(b), a commenter was not clear whether these additional provisions apply to all hospital patients admitted for any service if the hospital also has comprehensive medical rehabilitation services available or only inpatients admitted for medical rehabilitation services.

Response: The commission agrees with the commenter that the rule was not clear, and has added "applicable to patients who receive such services" to §133.42(b), (c) and (d) to clarify what is required of hospitals.

Comment: Concerning §133.44(b)(1), a commenter stated that the requirement to identify staff that has authority to represent that hospital and the physician is much needed.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.44(b)(2), a commenter stated that the inclusion of state mental hospitals in transfer agreements is long overdue.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(3), a commenter recommended that the regulation designate the local public health authority rather than the local disaster management authority.

Response: The commission disagrees with the commenter. Local disaster management authority is not defined. The local disaster management authority may be public health, if that is who the community commonly understands to be in control. Generally it is the City Emergency Management Office. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(A), a commenter objected to the all-hazard disaster plan being sent to the board of managers or the governing body.

Response: The commission disagrees with the commenter. The rule requiring developing the plan through a joint effort of the hospital governing body, administration, medical staff, and hospital personnel has been in effect since August 13, 1998. The proposed rule adds the participation of the emergency medical services partners. The level of participation is not defined and is left to the members of the group to decide. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(C), a commenter recommended that hospitals be required to consider the availability of sources of potable water and/or water to flush toilets under emergency conditions. The commenter recommended, at the very least, that the hospital's emergency plan include emergency contact information for their water supplier.

Response: The commission agrees with the commenter and has added "and the hospital water supplier" to §133.45(c)(4)(C). The provision of an emergency water supply is required by §133.162(d)(4)(A)(i)(VIII).

Comment: Concerning §133.45(c)(4)(D), a commenter objected to a rule requiring the after action report be available for review by the local emergency management authority and the Department of State Health Services (DSHS). The responsibility for a hospital's after action reports rests with the hospital authorities within the institution. Reports are provided for review during state level inspections and during accreditation visits. A more appropriate way to phrase this is to have hospitals participate in local exercises and the follow-up after-action review on a community wide basis.

Response: The commission disagrees with the commenter. The plan is required to be developed through a joint effort of the hospital governing body, administration, medical staff, hospital personnel and emergency medical services partners. All members of the group need to participate in testing the all-hazard plan, identifying deficiencies, and taking corrective actions to continuously improve the effectiveness of the plan. The commenter stated that reports are provided for review during state level inspections. These inspections are conducted by DSHS staff. No

change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(F), a commenter objected to this being a licensing rule. This should be a recommendation, not a requirement. Hospitals have back up generators that are tested regularly and this is reviewed by the JCAHO. The facility tests radios monthly; however, the decision on how the hospital communicates with the local utility company is better left to the hospital.

Response: The commission disagrees with the commenter. During a disaster, there may be a limited supply of fuel available for generators. During hurricane Rita, it was identified that hospitals need to have a plan for and to be given priority for the restoration of utility and phone services. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(G)(ii), a commenter recommended replacing the comma with "and" to clarify that there are two reporting categories rather than three.

Response: The commission agrees with the commenter and has replaced the comma with "and", deleted "and" and added "that are".

Comment: Concerning §133.45(c)(4)(H)(i)(I), a commenter objected to this being a licensing requirement. This is better handled locally. Employees have identification (ID) badges they can show the police and access should be granted without further action. A statement to that effect is on the back of the employee ID.

Response: The commission agrees with the commenter that this meets the intent of the rule, but disagrees with the commenter that this should not be a licensing requirement. During hurricane Rita, hospital staff had problems accessing their delivery care sites even with ID badges. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(H)(i)(II), a commenter objected to this being a licensing requirement. Hospitals already have personal protection equipment and the staff uses it daily. The decision should be a local one based upon the situation. The immunization of staff already occurs but staff can refuse to be vaccinated. Volunteers and families should see their personal physician or public health to receive vaccinations.

Response: The commission agrees with the commenter that this meets the intent of the rule, but disagrees with the commenter that this should not be a licensing requirement. During hurricane Rita, it was identified that hospitals need to include these requirements in the all-hazard disaster preparedness plan. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(H)(i)(II), two commenters recommended the rule be revised to give hospitals the discretion to determine which staff, volunteers or others are provided equipment or are immunized. In the development of the disaster plan a hospital must consider its needs, priorities and potential resources that are available in these situations and must have the flexibility to make decisions on resource allocation.

Response: The commission agrees with the commenters and has added "appropriate" to describe the provision of personal protection equipment.

Comment: Concerning §133.45(c)(4)(H)(i)(III), a commenter objected to this being a licensing requirement. It should be a recommendation. Not every hospital has a preparation area, not every hospital has staff to prepare food (contract pre-made meals for example) and some hospitals may have very limited storage capability.

Response: The commission disagrees with the commenter. During hurricane Rita, it was identified that a critical component of the all-hazard disaster preparedness plan must be a plan to provide food and shelter for staff and volunteers as needed throughout the duration of the response. Such an approach will aid the hospital in developing a scalable response capability, and in defining the timing and criteria for decisions involving sheltering in place, patient transfer, facility closing, or evacuation. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(H)(ii)(II), a commenter objected to this being a licensing requirement. "Evacuation" evokes the image of a disaster situation and in such a matter, the situation will dictate processes outside the control of the hospital. Patients are transferred on a daily basis and procedures are set up. However, in a disaster situation it may not be possible to know where the patients are going, what means of conveyance will be available or what the capabilities of the receiving facility may be.

Response: The commission disagrees with the commenter. The rule recognizes that this part of the evacuation component of the all-hazard disaster preparedness plan is within control of the hospital. Planning must address managing and maintaining the hospital, but also must consider evacuation of the entire facility when the environment is no longer deemed safe. To transport patients safely during an emergency, the planning process must consider advance communication with the alternate care site or sites. The plan should also recognize that a contingency plan may be necessary in a disaster. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(H)(ii)(III), a commenter objected to this being a licensing requirement. It should be a recommendation. In a disaster situation, the phones could be down and the patients may need to be evacuated immediately. There would not be time for someone to go through the medical records and call each patient's family. And the destination may not be known.

Response: The commission disagrees with the commenter. The rule does not include a time frame or the method of notification of patient emergency contacts of an evacuation and the patient's destination. During hurricane Rita, it was identified that a plan is needed to accomplish this notification. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(H)(ii)(IV), a commenter objected to this being a licensure requirement. It should be a recommendation. It is understood that these records should go with the patient. Wrist bands are shower proof already. In a disaster it may not be feasible to send all this information. Copy machines and computers may be down. A one page hand written summary of care may be all that time permits.

Response: The commission disagrees with the commenter. During hurricane Rita, it was identified that, when the environment cannot support adequate care, treatment, and services, to transport patients safely during an emergency, the evacuation component of the all-hazard disaster preparedness plan must include these items.

Comment: Concerning §133.161(a)(1)(B), a commenter recommended that it be clarified that existing hospitals are allowed to continue to meet requirements in effect at the time of construction. The proposed wording seems to require older existing facilities to comply with the 2003 edition of the NFPA 101, Chapter 19. This requirement could be cost prohibitive to bring a pre-1967 building up to the 2003 NFPA Code, causing hospitals to close.

Response: The commission disagrees with the commenter. CMS requires existing hospitals to comply with NFPA 101, LSC, Chapter 19 (Existing Health Care Occupancies), 2000 edition. The proposed rules adopt NFPA 101, Chapter 19, 2003 edition. The proposed rules clearly state that existing hospitals must comply with life safety code requirements that were in affect at the time the hospital was constructed. However, NFPA 101, Chapter 19, 2003 edition does incorporate code requirements from previous years' editions of the NFPA 101, which basically enables existing facilities to comply with all life safety code requirements. This requirement will not be cost prohibitive causing hospitals to close. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.162, a commenter recommended that, before the new construction requirements are adopted in final form, a cost analysis should be performed, and greater flexibility should be incorporated into the requirements. It was the general opinion of members that the new construction requirements, in general that increased spatial requirements, particularly in the emergency suite and the obstetrical suite, could increase space needed by 20-30%. In addition, in the rehabilitation therapy suite, there are requirements for separate offices for physical and occupational therapists, which in small hospitals are usually shared work areas. There are other instances of designating spaces for "exclusive use" which in small hospitals may not warrant exclusive use areas due to the low volume of patients or staffing needs. Members believe that the sharing of space for a variety of purposes should be allowed, as long as the effective, efficient, and safe delivery of care can be demonstrated by the hospital. It appears to members that the new construction requirements may be unnecessary, unduly burdensome and may prevent small hospitals from being able to undergo new construction due to rigid increased space specifications.

Response: The commission disagrees with the commenter. The proposed rules track and follow closely, the spatial requirements of the American Institute of Architects Academy of Architecture for Health, Guidelines for Design and Construction of Health Care Facilities, 2006 edition (AIA Guidelines). The workgroup's focus was to assure minimal requirements and to follow national standards and trends for healthcare facilities. Spatial increases were included in the proposed rules in order to accommodate the use of more healthcare equipment during the delivery of care and services to patients and to ensure an adequate work environment. Throughout the rules, "when" language is utilized to address situations that result in a hospital providing a certain type of service that is beyond the requirements of a minimal hospital. When a hospital elects to provide a specific type of service, then the requirements for that particular service is defined in the rules. The rules do not prohibit individuals such as a physical therapist and an occupational therapist from sharing the same office space. If one individual "wears many hats", then one office is probably appropriate. One major difference between the licensing rules and the AIA Guidelines is that the AIA Guidelines will require all future constructed patient sleeping rooms to be private. The reason the healthcare industry is enlarging the private room and making it suitable for only single occupancy is for infection control purposes and to meet handicap requirements. The proposed rules still allow for the construction of semiprivate rooms in new hospitals. The "exclusive" language in the proposed rules is used primarily for infection control purposes and closely mirrors national standards such as the AIA Guidelines. There would be no benefit gained by conducting a cost analysis because every hospital in Texas is unique in its size, scope, and location. The square foot costs continue to increase each year in hospitals. There are no two hospitals alike, and each year the size and spatial environment for new construction has increased in order to meet market demands. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.162(d)(4)(A)(i)(VIII), two commenters generally support the need for hospitals to have an appropriate emergency water supply, however, the prohibition on the use of bottled water is unnecessary and will limit hospitals' ability to address their water needs in emergency situations. The commenters requested deletion of the sentence that disallows the use of bottled water.

Response: The commission agrees with the commenters and is therefore modifying the language at §133.162(d)(4)(A)(i)(VIII). The department's primary concern is that a hospital has an adequate water supply to meet the needs of patients during an emergency situation. Each hospital is required to provide not less than 500 gallons or 12 gallons of water per licensed patient bed. For example, a hospital with 100 patient beds is required to have 1,200 gallons of water on site at all times for emergency purposes. The hospital must ensure that it maintains an adequate supply of bottled water at all times, maintains an inventory record which reflects the rotation and replacement of expired bottled water, and have adequate storage space on site that is readily accessible by staff in the event of an emergency. The hospital must ensure the continued availability and delivery of bottled water until the emergency situation has concluded.

Comment: Concerning §133.162(d)(4)(A)(iii)(IV), two commenters requested deletion of the qualifications of the personnel who will conduct the verification tests and inspections until the impact of this requirement can be assessed. This proposed requirement was not included in prior drafts of the rules, and the commenters are concerned that this personnel standard may not be attainable by hospitals, particularly those hospitals located in rural areas of the state. The personnel required by this proposed rule to verify proper installation of these systems may not be available to rural and small community hospitals in their community or surrounding area. Bringing such personnel to hospitals in rural areas may be cost prohibitive, and may create an unfair financial burden on hospitals in those rural areas where such experts are not available.

Response: The commission disagrees with the commenters. In the 03/02/06 proposed rules that the council recommended the Executive Commissioner's approval for publication in the Texas Register, the NFPA 99 reference was updated from §4-3 to §5.1 in §133.162(d)(4)(A)(iii). NFPA 99, Chapter 5, 2002 edition, requires professional qualifications for medical gas verifiers to meet American Society of Safety Engineers (ASSE) Personnel Standard 6030, Professional Qualifications Standard for Medical Gas Systems. It was critical for this language to be incorporated in the proposed rules for clarity. A third party qualified to do the testing did all previous gas verification. Verifiers are now required to meet ASSE Personnel Standard 6030 qualification and to carry the certification card. The verification testing is necessary to assure patient safety and that medical gas systems

have been tested by a qualified individual. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.163(c)(1)(B)(iii), a commenter asked if it is mandatory to have a locker room in a small facility.

Response: It is not mandatory to have a locker room in the central sterile supply suite. However, if the hospital chooses to provide a locker room in the central sterile supply suite, compliance with this rule is required. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.163(c)(1)(B)(iv), a commenter questioned whether the housekeeping room in the central sterile supply suite should be on the decontamination/soiled side and/or on the sterile supply/clean side, as it was not mentioned in the rules.

Response: The commission agrees with the commenter and has clarified that the housekeeping room shall be located on the decontamination/soiled side of the central sterile supply suite.

Comment: Concerning §133.163(d)(1)(B)(v) and §133.163(d)(1)(D)(ii), a commenter indicated that the distance requirements are in conflict.

Response: The commission disagrees with the commenter. The rule at §133.163(d)(1)(B)(v) applies to open ward environments in adult and pediatric units. The rule at §133.163(d)(1)(D)(ii) applies to a multiple-bassinet/crib (sleeping unit) room/ward. The two specific sleeping unit types constitute the differences in the requirements. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.163(k), a commenter recommended eliminating the proposed language and requiring that hyperbaric facilities conform either to the specific language of the Associates of the Undersea and Hyperbaric Medical Society, Hyperbaric Facility Design Guidelines, Version 1.0, July 2004, or the American Institute of Architects 2006 Guidelines for Design and Construction of Health Care Facilities standard for hyperbaric suites. The commenter stated that the current standard and proposed changes contain ambiguous language with respect to hyperbaric chambers, ignore one entire class of hyperbaric chamber, and require inter-chamber spacing distances that have essentially no impact on patient care, yet increase the cost of facility construction.

Response: The commission disagrees with the commenter that the proposed language should be eliminated and that hyperbaric facilities should be required to conform either to the specific language of the Associates of the Undersea and Hyperbaric Medical Society, Hyperbaric Facility Design Guidelines, Version 1.0, July 2004, or the American Institute of Architects 2006 Guidelines for Design and Construction of Health Care Facilities standard for hyperbaric suites. The AIA Guidelines recommend in the appendix that the standard for hyperbaric suites should meet the requirements of the Associates of the Undersea and Hyperbaric Medical Society, Hyperbaric Facility Design Guidelines, Version 1.0, July 2004. The AIA Guidelines have not adopted the Associates of the Undersea and Hyperbaric Medical Society, Hyperbaric Facility Design Guidelines. The AIA Guidelines only recommend that it be reviewed in its appendix. The proposed rules have adopted the NFPA 99, Chapter 20, Hyperbaric Facilities, 2002 edition. The department has added, "Multiple occupancy chambers (Class A) shall be in accordance with NFPA 99, Chapter 20" in §133.163(k)(1)(A). This standard for Class A chambers was inadvertently left out of the proposed rules. The department has reworded the next sentence to clarify that the minimum clearance is from the side of a chamber to a wall/partition, and reduced the distance requirement from five feet to three feet as the distance was excessive. The phrase "foot of the chamber" was changed to "chamber entry" to clarify the configuration of the chamber entry point.

Comment: Concerning §133.163(u)(1)(Q)(iv) and §133.163(ee)(1)(G)(iii), a commenter questioned the requirement of providing viewing panels from the scrub area into the caesarean section (c-section) room and the operating room. The commenter has been asked by hospitals to remove existing viewing panels from scrub areas into operating rooms because of the privacy law.

Response: The commission disagrees with the commenter. The requirement for a viewing panel into the c-section room has been a requirement since 1985. New language has been added to require the viewing panel into operating rooms. The workgroup concurs with the AIA Guidelines, which require there to be a viewing panel from the scrub area into the operating room. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.163(v)(1)(F)(iii), a commenter stated that the requirement for the clearance between a side of lounger/gurney and a wall/partition to be a minimum of three feet six inches in each secondary recovery station conflicts with Diagram D in §133.169(h).

Response: The commission agrees with the commenter and has corrected three feet six inches to three feet.

Comment: Concerning §133.163(x), two commenters recommended requiring pharmacies to be in compliance with the rules of the Texas State Board of Pharmacy, as the proposed rules may be in conflict with 22 Texas Administrative Code, §291.26 (relating to Pharmacies Compounding Sterile Pharmaceuticals) and the United States Pharmacopoeia, Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

Response: The commission agrees with the commenters and has made the recommended changes to comply with 22 Texas Administrative Code, §291.26, (relating to Pharmacies Compounding Sterile Pharmaceuticals) and the United States Pharmacopoeia, Chapter 797, Pharmaceutical Compounding-Sterile Preparations. New language has been added for clarification purposes and to conform to the United States Pharmacopoeia, Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

Comment: Concerning §133.163(ee)(1)(D), a commenter indicated that in facilities with two or more operating rooms the rule was silent as to a requirement for the number of preoperative patient holding area(s) or rooms. The commenter also indicated that the rule does not indicate that preoperative beds can swing to recovery beds.

Response: The commission agrees with the commenter. The workgroup indicated that each facility would determine the number of preoperative holding areas(s) or room(s) based on the workload of that facility. The workgroup also determined that these rooms should not be used as post-anesthesia care unit(s) (PACU), since the requirements for recovery and preoperative care are different. A patient coming out of anesthesia and a patient being prepared for surgery should not be in the same area. It was determined by the workgroup that the preoperative patient holding area(s) or room(s) could be used for secondary recov-

ery. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.165, ten commenters requested the deletion of the section until the various architectural and operational issues relating to multiple hospitals within the same facility can be appropriately reviewed and an alternative rule can be developed. This is a new section of the rules that was not included in prior drafts of changes to the licensing rules. Based on input received from member hospitals, there are numerous concerns with this section and how it might be interpreted and applied by the department. Many hospitals are utilizing the hospital within a hospital concept in an effort to expand the scope of services provided within their community. This concept also can be very cost-effective if the guest hospital as described in the proposed rules is allowed to obtain certain services from the host hospital. However, this proposed section will require the guest hospital to separately provide services, such as, imaging/diagnostic services, dietary services and laboratory services; thus, prohibiting the guest hospital from obtaining these services for its patients from the host hospital. In addition, this proposed section establishes unnecessary restrictions on the movement of patients between the guest and host hospitals.

Response: The commission disagrees with the commenters. Most guest hospitals are licensed as special hospitals. A special hospital is already mandated by the HSC, §241.003(15), to provide clinical laboratory facilities, diagnostic x-ray facilities, treatment facilities or other definitive medical treatment. The 03/02/06 proposed rules that the council recommended the Executive Commissioner's approval for publication in the *Texas Register* included the requirement for each hospital to provide imaging and other diagnostic services and facilities and laboratory services and a laboratory suite. The proposed rule requires each hospital also to provide dietary services and dietary suite, including staff dining facilities. The department determined this new requirement was necessary due to the sudden closure of several host hospitals over the past few years. Guest hospitals were left in a huge dilemma and unable to provide even minimal dietary services to inpatients. This proposed rule is only applicable to new construction. The new rule only requires the guest hospital to meet minimal dietary requirements. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.166(c)(1)(D), two commenters requested deletion of the requirement to provide a covered walkway or enclosure from the hospital to a mobile, transportable, or relocatable unit where inpatient services are provided. Based on comments received from member hospitals, it is the understanding of the commenters that measures currently are taken to protect inpatients from the elements when services are provided in these units. Strict compliance with this proposed section will unnecessarily increase hospital costs and will be cost prohibitive for small or rural hospitals. The strict enforcement of this proposed requirement is highly likely to cause hospitals to be unable to comply, which would result in the cessation of certain services in the rural areas, thus denying patients access to these services.

Response: The commission agrees with the commenters that, as long as a mobile, transportable or relocatable unit is utilized for outpatient purposes only, connection to the hospital is not required. The rule at §133.21(c)(2) states, "A hospital license shall not include off-site outpatient facilities." When a hospital wants outpatient services or any service to be part of the hospital license, a hospital shall be in a single building where inpatients and outpatients can receive hospital services as defined under "Premises" in §133.2(40). By providing a covered walkway or enclosure from a mobile, transportable or relocatable unit to a hospital, the mobile, transportable or relocatable unit can be considered as part of the hospital license. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.166(c)(1)(F), two commenters requested deletion of the requirement for the unit to be provided certain equipment and systems connected to the hospital, when a mobile, transportable, or relocatable unit is permanently connected appropriately for the climate to the hospital or the unit does not move on a regular basis. These mobile units provide access to care for many rural Texans, and this care has been safe. The units typically provide for fire safety and electrical back-up power independently. Many of the units provide only services which do not require a patient to have access to a medical gas system or nurse call system. Based on comments received from member hospitals, one of these commenters believes that the cost to comply with this proposed rule will range from $75,000 to $100,000. Compliance with this proposed section also will unnecessarily increase hospital costs and this requirement will be cost prohibitive for small or rural hospitals.

Response: The commission agrees with the commenters that, as long as a mobile unit provides outpatient services only, the requirement for equipment system connection to the hospital is not necessary. The rule at §133.21(c)(2) states, "A hospital license shall not include off-site outpatient facilities." When a hospital wants outpatient services or any service to be part of the hospital license, then the hospital shall be in a single building where inpatients and outpatients can receive hospital services as defined under "Premises" in §133.2(40). Once a mobile unit is providing services under the hospital license, it is considered a building and, therefore, required to be contiguous to the main building. For example, NFPA 72, which is the fire alarm code, requires the fire alarm to be one system in a hospital. The hospital licensing rules and NFPA 99, Standard for Health Care Facilities, require all medical gases to be a piped in single system and connected to the master alarm. NFPA 101, Life Safety Code, requires a hospital to have a wet sprinkler system and to be monitored at all times at a central location. NFPA 101 also requires the mobile unit to be connected to the emergency essential electrical system. All these physical equipment connections are necessary to assure the safety and protection of patients under one system. The commission has increased the number of days to describe a regular basis from every 30 days or less to every 90 days or less.

Comment: Concerning §133.169(c), a commenter requested that for x-ray (surgical/critical care, catheterization) the minimum air changes of outdoor air per hour not be increased from 3 to 4, and the minimum total air changes per hour not be increased from 15 to 20, as AIA and American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) still require 3 and 15.

Response: The commission agrees with the commenter and has maintained the requirements as in the current rules to reflect what is required by the AIA Guidelines and ASHRAE.

Comment: Concerning §133.169(c), two commenters recommended that the exhaust requirement be removed from the fluoroscopy room.

Response: The commission agrees with the commenters and has deleted the requirement. There is no qualitative reason to

exhaust all the air in this room. Prohibiting the recirculation by means of room units should not be a factor in providing quality air.

Comment: Concerning §133.169(c), Note 7, a commenter recommended a correction to the description of the temperature in relation to the humidity.

Response: The commission agrees with the commenter and has corrected the sentence to read, "The relative humidity is expected to be at the lower end of the range when the temperature is also at the higher end, and vice versa."

Comment: Concerning §133.169(f), a commenter could not find the minimum requirement of medical gas station outlets for a continuing care nursery.

Response: The commission disagrees with the commenter. Table 6 does contain the number of medical gas station outlets for each bassinet. No change has been made to the proposed Table 6 based on this comment.

The department staff and the commission have made the following changes that will correct errors, clarify the intent, and improve the accuracy of the chapter.

Concerning §133.21(c)(4)(A), the reference to §133.2(40) was revised to §133.2(41) due to renumbering.

Concerning §133.23(b)(1)(B), the phrase "that is dated no earlier than one year prior to the application date;" was deleted and added the sentence "The hospital fire safety survey shall be conducted annually and both surveys shall be submitted." This clarifies what is required of hospitals.

Concerning §133.41(i)(1)(C), the term "(HBV)-containing" was hyphenated to be consistent.

Concerning §133.41(j)(8)(C), the sentence "The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission." was added. This clarifies what is required of hospitals and is consistent with the Medicare CoPs.

Concerning §133.41(j)(8)(D), the rule text "an updated medical record entry documenting an examination for any changes in the patient's condition when the medical history and physical examination are completed within 30 days before admission. This updated examination must be completed and documented in the patient's medical record within 24 hours after admission." was inserted. This clarifies what is required of hospitals and is consistent with the Medicare CoPs. Subsequent subparagraphs were relettered.

Concerning §133.41(k)(3)(F), the sentence "The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission." was added. This clarifies what is required of hospitals and is consistent with the Medicare CoPs.

Concerning §133.41(o)(7)(B), the spelling of policies was corrected.

Concerning §133.41(q)(5)(B), the sentence "Drugs and biologicals shall be kept in a locked storage area." was deleted. The sentence "All drugs and biologicals must be kept in a secure area, and locked when appropriate." was added. This new language is consistent with the Medicare CoPs for Hospitals effective January 26, 2007. Since the goal is to be as consistent as possible with the CoPs, the change has been made. Section 241.026(b) requires us to consider the CoPs in adopting rules and attempt to achieve consistency with those conditions. This change is less stringent than the proposed language.

Concerning §133.41(q)(5)(B)(ii), the sentence "Dangerous drugs as well as controlled substances shall be secure from unauthorized use." was added. The sentence "Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area was added. This new language is consistent with the Medicare CoPs for Hospitals effective January 26, 2007. Since the goal is to be as consistent as possible with the CoPs, the change has been made. Section 241.026(b) requires us to consider the CoPs in adopting rules and attempt to achieve consistency with those conditions. This change is less stringent than the proposed language.

Concerning §133.162(d)(4), the title of the code was corrected to "National Standard Plumbing Code Illustrated" and corrected the year of the code from "2000" to "2003".

Concerning §133.162(d)(4)(A)(iii)(IV), the title of the standard and the contact information was corrected.

Concerning §133.163(f)(1)(A)(i)(II), the department has clarified that a multiple-bed emergency treatment room is not required by adding "When . . .is provided."

Concerning §133.163(f)(1)(B)(i)(IV), the word "room" was added after the words "patient toilet".

Concerning §133.163(f)(3), language was added to clarify that when performing surgery in a trauma room, the ventilation requirement is no different than in an operating room.

Concerning §133.163(k)(1), the chapter reference was corrected from "19" to "20".

Concerning §133.163(n)(3)(C)(iv), the number "twenty-four" was corrected to "24-hour".

Concerning §133.163(o), the word "may" was corrected to "shall" as the hospital is required to provide laundry service.

Concerning §133.163(r)(1)(A), the phrase "for a general hospital" was added. This had been discussed with the workgroup, and it was not changed in the proposed rules.

Concerning §133.163(t)(1)(C)(iv), the text "and in surgical suite post-anesthesia care units" was added after "CCU suites" as the requirements are the same and the wording had been inadvertently left out in the proposed rules.

Concerning §133.163(u)(1)(N)(i), the observation windows are to permit the viewing of infants from public areas for full-term nurseries and from workroom(s) into adjacent nurseries, and added that windows between nurseries may be provided for convenience of staff observation.

Concerning §133.163(u)(1)(O)(xx), the word "convenient" was changed to the word "conveniently".

Concerning §133.163(u)(1)(Q)(vi), the words "small style D or E" were added to define the medical gas cylinder size.

Concerning §§133.163(u)(1)(Q)(xii), (dd)(1)(B)(iv) and (C)(vi), the word "appropriate" was changed to the word "appropriately". Concerning §133.163(u)(2)(A)(v) and (vi), the word "an" was corrected to the word "a".

Concerning §133.163(u)(2)(B)(iii), the rule was corrected by adding "isolation and anteroom" as this was inadvertently left out in the proposed rules.

Concerning §133.163(u)(4)(B)(iii), the word "provide" to "provided in".

Concerning §133.163(v)(1)(A), to clarify the rule language was added,"To be included in the hospital license," and the words "If", 'is" and "that portion" were deleted. The word "contains" was corrected to "contain". The sentence, "When an outpatient facility is not located contiguous to the hospital and does not provide services for the hospital patients, it is not considered part of the licensed hospital and will not need to comply with these licensing rules" was deleted because of redundancy.

Concerning §133.163(y)(2)(A)(ii), the repetitive phrase "in design or shielding" was deleted.

Concerning §133.163(ff)(2)(A)(ii), the sentence was corrected to read as "shall have" hardware that minimizes jamming possibilities is required.

Concerning §133.169(c), the spelling of hospital was corrected in the title, changed "IV preparation room" to "preparation/anteroom," changed "chemo-hood room" to "chemotherapy room-fume hoods," changed the exhaust requirement for the preparation/anteroom, and added the IV hood room to comply with the United States Pharmacopoeia, Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

Concerning §133.169(e), the temperature was changed from "110" to "105-120" in the hot water use table to provide a minimum and a maximum range of temperature for clinical areas in lieu of a fixed temperature, which is extremely hard to attain at all times. This is also the range indicated in the AIA guidelines.

Concerning §133.169(f), the medical gas station outlet headings for oxygen and vacuum was corrected by adding the numerical note "4" as it had been inadvertently left out in the proposed rules.

Concerning §133.169(g), "Note 10" was added to clarify the quantities of code blue devices required where there are multi-beds in an open ward. Note 10 was also added in the appropriate areas in the staff emergency assistance calling system (code blue) column. Corrections have been made to location titles to be consistent with the rules and intermediate care suite was moved to be in the same order as the rules.

LEGAL CERTIFICATION

The Department of State Health Services Deputy General Counsel, Lisa Hernandez, certifies that the rules, as adopted, have been reviewed by legal counsel and found to be a valid exercise of the agencies' legal authority.

SUBCHAPTER A. GENERAL PROVISIONS

25 TAC §133.1, §133.2

STATUTORY AUTHORITY

The repeals are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

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Lisa Hernandez
Deputy General Counsel
Department of State Health Services
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25 TAC §133.1, §133.2

STATUTORY AUTHORITY

The new sections are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

§133.2. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Hospital Licensing Law, Health and Safety Code, Chapter 241.

(2) Action plan--A written document that includes specific measures to correct identified problems or areas of concern; identifies strategies for implementing system improvements; and includes outcome measures to indicate the effectiveness of system improvements in reducing, controlling or eliminating identified problem areas.

(3) Advanced practice nurse (APN)--A registered nurse who is currently licensed and authorized by the Board of Nurse Examiners for the State of Texas to practice as a nurse practitioner, nurse-midwife, nurse anesthetist, or clinical nurse specialist.

(4) Adverse event--An event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.

(5) Applicant--The person legally responsible for the operation of the hospital, whether by lease or ownership, who seeks a hospital license from the department.

(6) Available--When referring to on-site personnel, on the premises and able to rapidly perform hands-on care in an emergency situation.

(7) Chemical dependency services--A planned, structured, and organized program designed to initiate and promote a person's chemical-free status or to maintain the person free of illegal drugs. It includes, but is not limited to, the application of planned procedures to identify and change patterns of behavior related to or resulting from chemical dependency that are maladaptive, destructive, or injurious to health, or to restore appropriate levels of physical, psychological, or social functioning lost due to chemical dependency.

(8) Community-wide plan--An agreement entered into between one or more health care facilities, entities administering a sexual assault program, district attorney's offices, or law enforcement agencies that designates one or more health care facilities in the community as a primary health care facility to furnish emergency medical services and evidence collection to sexual assault survivors on a community or area-wide basis.

(9) Comprehensive medical rehabilitation--The provision of rehabilitation services that are designed to improve or minimize a person's physical or cognitive disabilities, maximize a person's functional ability, or restore a person's lost functional capacity through close coordination of services, communication, interaction, and integration among several professions that share responsibility to achieve team treatment goals for the person.

(10) Comprehensive medical rehabilitation hospital--A general hospital that specializes in providing comprehensive medical rehabilitation services, including surgery and related ancillary services.

(11) Comprehensive medical rehabilitation unit--An identifiable part of a hospital which provides comprehensive medical rehabilitation services to patients admitted to the unit.

(12) Cooperative agreement--An agreement among two or more hospitals for the allocation or sharing of health care equipment, facilities, personnel, or services.

(13) Dentist--A person licensed to practice dentistry by the Texas State Board of Dental Examiners. This includes a doctor of dental surgery or a doctor of dental medicine.

(14) Department--The Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756-3199.

(15) Dietitian--A person who is currently licensed by the Texas State Board of Examiners of Dietitians as a licensed dietitian or provisional licensed dietitian, or who is a registered dietitian with the American Dietetic Association.

(16) Director--The hospital licensing director, Department of State Health Services.

(17) Emergency medical condition--A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in one or all of the following:

(A) placing the health of the individual (or with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

(B) serious impairment to bodily functions;

(C) serious dysfunction of any bodily organ or part; or

(D) with respect to a pregnant woman who is having contractions:

(i) that there is inadequate time to effect a safe transfer to another hospital before delivery; or

(ii) that transfer may pose a threat to the health or safety of the woman or the unborn child.

(18) General hospital--An establishment that:

(A) offers services, facilities, and beds for use for more than 24 hours for two or more unrelated individuals requiring diagnosis, treatment, or care for illness, injury, deformity, abnormality, or pregnancy; and

(B) regularly maintains, at a minimum, clinical laboratory services, diagnostic X-ray services, treatment facilities including surgery or obstetrical care or both, and other definitive medical or surgical treatment of similar extent.

(19) Governing body--The governing authority of a hospital which is responsible for a hospital's organization, management, control, and operation, including appointment of the medical staff; includes the owner or partners for hospitals owned or operated by an individual or partners.

(20) Governmental unit--A political subdivision of the state, including a hospital district, county, or municipality, and any department, division, board, or other agency of a political subdivision.

(21) Hospital--A general hospital or a special hospital.

(22) Hospital administration--Administrative body of a hospital headed by an individual who has the authority to represent the hospital and who is responsible for the operation of the hospital according to the policies and procedures of the hospital's governing body.

(23) Inpatient--An individual admitted for an intended length of stay of 24 hours or greater.

(24) Inpatient services--Services provided to an individual admitted to a hospital for an intended length of stay of 24 hours or greater.

(25) Licensed vocational nurse (LVN)--A person who is currently licensed under the Nursing Practice Act by the Board of Nurse Examiners for the State of Texas as a licensed vocational nurse or who holds a valid vocational nursing license with multi-state licensure privilege from another compact state.

(26) Licensee--The person or governmental unit named in the application for issuance of a hospital license.

(27) Medical staff--A physician or group of physicians and a podiatrist or group of podiatrists who by action of the governing body of a hospital are privileged to work in and use the facilities of a hospital for or in connection with the observation, care, diagnosis, or treatment of an individual who is, or may be, suffering from a mental or physical disease or disorder or a physical deformity or injury.

(28) Mental health services--All services concerned with research, prevention, and detection of mental disorders and disabilities and all services necessary to treat, care for, supervise, and rehabilitate persons who have a mental disorder or disability, including persons whose mental disorders or disabilities result from alcoholism or drug addiction.

(29) Mental retardation--Significantly subaverage general intellectual functioning that is concurrent with deficits in adaptive behavior and originates during the developmental period.

(30) Niche hospital--A hospital that:

(A) classifies at least two-thirds of the hospital's Medicare patients or, if data is available, all patients:

(i) in not more than two major diagnosis-related groups; or

(ii) in surgical diagnosis-related groups;

(B) specializes in one or more of the following areas:

(i) cardiac;

(ii) orthopedics;

(iii) surgery; or

(iv) women's health; and

(C) is not:

(i) a public hospital;

(ii) a hospital for which the majority of inpatient claims are for major diagnosis-related groups relating to rehabilitation, psychiatry, alcohol and drug treatment, or children or newborns; or

(iii) a hospital with fewer than 10 claims per bed per year.

(31) Outpatient--An individual who presents for diagnostic or treatment services for an intended length of stay of less than 24 hours; provided, however, that an individual who requires continued observation may be considered as an outpatient for a period of time not to exceed a total of 48 hours.

(32) Outpatient services--Services provided to patients whose medical needs can be met in less than 24 hours and are provided within the hospital; provided, however, that services that require continued observation may be considered as outpatient services for a period of time not to exceed a total of 48 hours.

(33) Owner--One of the following persons or governmental unit which will hold or does hold a license issued under the statute in the person's name or the person's assumed name:

(A) a corporation;

(B) a governmental unit;

(C) a limited liability company;

(D) an individual;

(E) a partnership if a partnership name is stated in a written partnership agreement or an assumed name certificate;

(F) all partners in a partnership if a partnership name is not stated in a written partnership agreement or an assumed name certificate; or

(G) all co-owners under any other business arrangement.

(34) Patient--An individual who presents for diagnosis or treatment.

(35) Pediatric and adolescent hospital--A general hospital that specializes in providing services to children and adolescents, including surgery and related ancillary services.

(36) Person--An individual, firm, partnership, corporation, association, or joint stock company, and includes a receiver, trustee, assignee, or other similar representative of those entities.

(37) Physician--A physician licensed by the Texas Medical Board.

(38) Physician assistant--A person licensed as a physician assistant by the Texas State Board of Physician Assistant Examiners.

(39) Podiatrist--A podiatrist licensed by the Texas State Board of Podiatric Medical Examiners.

(40) Practitioner--A health care professional licensed in the State of Texas, other than a physician, podiatrist, or dentist. A practitioner shall practice in a manner consistent with their underlying practice act.

(41) Premises--A premises may be any of the following:

(A) a single building where inpatients receive hospital services; or

(B) multiple buildings where inpatients receive hospital services provided that the following criteria are met:

(i) all buildings in which inpatients receive hospital services are subject to the control and direction of the same governing body;

(ii) all buildings in which inpatients receive hospital services are within a 30-mile radius of the primary hospital location;

(iii) there is integration of the organized medical staff of each of the hospital locations to be included under the single license;

(iv) there is a single chief executive officer for all of the hospital locations included under the license who reports directly to the governing body and through whom all administrative authority flows and who exercises control and surveillance over all administrative activities of the hospital;

(v) there is a single chief medical officer for all of the hospital locations under the license who reports directly to the governing body and who is responsible for all medical staff activities of the hospital;

(vi) each hospital location to be included under the license that is geographically separate from the other hospital locations contains at least one nursing unit for inpatients which is staffed and maintains an active inpatient census, unless providing only diagnostic or laboratory services, or a combination of diagnostic or laboratory services, in the building for hospital inpatients; and

(vii) each hospital that is to be included in the license complies with the emergency services standards:

(I) for a general hospital, if the hospital provides surgery or obstetrical care or both; or

(II) for a special hospital, if the hospital does not provide surgery or obstetrical care.

(42) Presurvey conference--A conference held with department staff and the applicant or the applicant's representative to review licensure rules and survey documents and provide consultation prior to the on-site licensure inspection.

(43) Psychiatric disorder--A clinically significant behavioral or psychological syndrome or pattern that occurs in an individual and that is typically associated with either a painful syndrome (distress) or impairment in one or more important areas of behavioral, psychological, or biological function and is more than a disturbance in the relationship between the individual and society.

(44) Quality improvement--A method of evaluating and improving processes of patient care which emphasizes a multidisciplinary approach to problem solving, and focuses not on individuals, but systems of patient care which might be the cause of variations.

(45) Registered nurse (RN)--A person who is currently licensed by the Board of Nurse Examiners for the State of Texas as a registered nurse or who holds a valid registered nursing license with multi-state licensure privilege from another compact state.

(46) Special hospital--An establishment that:

(A) offers services, facilities, and beds for use for more than 24 hours for two or more unrelated individuals who are regularly admitted, treated, and discharged and who require services more intensive than room, board, personal services, and general nursing care;

(B) has clinical laboratory facilities, diagnostic X-ray facilities, treatment facilities, or other definitive medical treatment;

(C) has a medical staff in regular attendance; and

(D) maintains records of the clinical work performed for each patient.

(47) Stabilize--With respect to an emergency medical condition, to provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility, or that the woman has delivered the child and the placenta.

(48) Transfer--The movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who has been declared dead, or leaves the facility without the permission of any such person.

(49) Universal precautions--Procedures for disinfection and sterilization of reusable medical devices and the appropriate use of infection control, including hand washing, the use of protective barriers, and the use and disposal of needles and other sharp instruments as those procedures are defined by the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services. This term includes standard precautions as defined by CDC which are designed to reduce the risk of transmission of blood borne and other pathogens in hospitals.

(50) Violation--Failure to comply with the licensing statute, a rule or standard, special license provision, or an order issued by the commissioner of state health services (commissioner) or the commissioner's designee, adopted or enforced under the licensing statute. Each day a violation continues or occurs is a separate violation for purposes of imposing a penalty.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

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SUBCHAPTER B. HOSPITAL LICENSE

25 TAC §133.21 - 133.26

STATUTORY AUTHORITY

The repeals are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

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25 TAC §§133.21 - 133.26

STATUTORY AUTHORITY

The new sections are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

§133.21. General.

(a) License required.

(1) A hospital shall obtain a license prior to admitting patients.

(2) Upon written request, the Department of State Health Services (department) shall furnish a person with an application for a hospital license.

(3) The license application shall be submitted in accordance with §133.22 of this title (relating to Application and Issuance of Initial License). The applicant shall retain copies of all application documents submitted to the department.

(b) Compliance. A hospital shall comply with the provisions of the Act and this chapter during the licensing period.

(c) Scope of hospital license.

(1) A hospital license is issued for the premises and person or governmental unit named in the application.

(2) A hospital license shall not include off-site outpatient facilities.

(3) Multiple hospitals may share one building.

(A) Each hospital shall be licensed separately.

(B) No part of the building may be dually licensed by more than one hospital; and

(C) Each hospital in the building shall comply with the requirements of §133.165 of this title (relating to Building with Multiple Occupancies).

(4) Multiple hospitals may be licensed under one license provided the following conditions are met.

(A) The hospitals must comply with the requirements for multiple hospitals under a single license as specified under §133.2(41) of this title (relating to Definitions).

(B) Each hospital location under the hospital license must;

(i) provide emergency services in compliance with §133.41(e) of this title (relating to Hospital Functions and Services); and

(ii) meet the requirements as an existing hospital in accordance with §133.161 of this title (relating to Requirements for Buildings in Which Existing Licensed Hospitals are Located) as determined by the department; or

(iii) meet the requirements of a new hospital in accordance with §133.162 of this title (relating to New Construction Requirements) as determined by the department.

(C) The administration of the primary hospital location must submit to the department the following:

(i) a complete and accurate multiple-location application;

(ii) a licensing fee for the number of design beds at the multiple-location hospital in accordance with §133.26(b) of this title (relating to Fees);

(iii) a copy of a hospital fire safety survey of the multiple-location hospital indicating approval by the local fire authority in whose jurisdiction the hospital is based that is dated no earlier than one year prior to the multiple-location application; and

(iv) if the main hospital is accredited by a Centers for Medicare and Medicaid Services-approved organization, a letter extending the accreditation of the main hospital to the multiple location.

(D) If a change of ownership is concurrent with the request for a hospital to become a multiple location of another, the department will require the new owners to submit the documents in subparagraph (C) of this paragraph and a signed copy of the bill of sale or lease agreement that reflects the effective date of the sale or lease. No change of ownership application will be required.

(5) A hospital license and an ambulatory surgical center license shall not be issued for the same premises.

(d) Display. A hospital shall prominently and conspicuously display the hospital license in a public area of the licensed premises that is readily visible to patients, employees, and visitors.

(e) Alteration. A hospital license shall not be altered.

(f) Transfer or assignment prohibited. A hospital license shall not be transferred or assigned. The hospital shall comply with the provisions of §133.24 of this title (relating to Change of Ownership) in the event of a change in the ownership of a hospital.

(g) Changes which affect the license.

(1) A hospital shall notify the department in writing prior to the occurrence of any of the following:

(A) addition or deletion of those services indicated on the license application;

(B) changes in design bed capacity as the phrase is used in §133.26(b)(1)(A) - (C) of this title;

(C) request to change license classification; and

(D) any construction, renovation, or modification of the hospital buildings.

(2) A hospital shall notify the department in writing at the time of the occurrence of any of the following:

(A) cessation of operation of the hospital. The hospital shall include in the written notice the location where the medical records will be stored and the identity and telephone number of the custodian of the medical records;

(B) change in certification or accreditation status;

(C) change in hospital name, telephone number or administrator; and

(D) change in the emergency contact name and phone number.

§133.23. Application and Issuance of Renewal License.

(a) Renewal notice. The Department of State Health Services (department) shall send a renewal notice to a hospital at least 60 calendar days before the expiration date of a license.

(1) If the hospital has not received the renewal notice from the department within 45 calendar days prior to the expiration date, it is the duty of the hospital to notify the department and request a renewal application for a license.

(2) If the hospital fails to submit the application and fee within 15 calendar days prior to the expiration date of the license, the department shall send by certified mail to the hospital a letter advising that unless the license is renewed, the hospital must cease operations upon the expiration of the hospital's license.

(b) Renewal license. The department shall issue a renewal license to a hospital which meets the minimum requirements for a license.

(1) The hospital shall submit the following to the department prior to the expiration date of the license:

(A) a complete and accurate application form;

(B) a copy of a hospital fire safety survey indicating approval by the local fire authority in whose jurisdiction the hospital is based. The hospital fire safety survey shall be conducted annually and both surveys shall be submitted.

(C) the renewal license fee;

(D) if the applicant is accredited by a Centers for Medicare and Medicaid Services-approved organization, a copy of documentation from the accrediting body showing the current accreditation status of the hospital; and (E) the following ownership information:

(i) the name and social security number of the sole proprietor, if the applicant is a sole proprietor;

(ii) the name and social security number of each partner who is an individual, if the applicant is a partnership;

(iii) the name and social security number of any individual who has an ownership interest of more than 25% in the corporation, if the applicant is a corporation; and

(iv) if the applicant is a niche hospital, the names and license numbers of any physicians licensed by the Texas Medical Board who have a financial interest in the applicant or any entity which has an ownership interest in the applicant.

(2) The department may conduct an inspection prior to issuing a renewal license in accordance with §133.101 of this title (relating to Inspection and Investigation Procedures).

(3) Renewal licenses will be valid for 24 months.

(c) Notice to cease operation and return license. If a hospital fails to submit the application, documents, and fee by the expiration date of the hospital's license, the department shall notify the hospital by certified mail that it must cease operation and immediately return the license by certified mail to the department. If the hospital wishes to provide services after the expiration date of the license, it shall apply for a license under §133.22 of this title (relating to Application and Issuance of Initial License).

§133.26. Fees.

(a) General.

(1) All fees paid to the Department of State Health Services (department) are nonrefundable with the exception of inspection fees for inspections that were not conducted.

(2) All fees shall be paid by check or money order made payable to the Department of State Health Services.

(b) License fees.

(1) The fee for an initial license or a renewal license is $39 per bed based upon the design bed capacity of the hospital. The design bed capacity of a hospital is determined as follows.

(A) The design bed capacity is the maximum number of patient beds that a hospital can accommodate in rooms that comply with the requirements for patient room suites in §133.163 of this title (relating to Spatial Requirements for New Construction) including beds, bassinets or cribs in critical care units (including neonatal nurseries), continuing care nursery beds, hospital-based skilled nursing units, medical nursing units, mental health and chemical dependency nursing units, pediatric and adolescent nursing units, obstetrical suites (including labor/delivery/recovery/postpartum (LDRP) beds), intermediate care beds, universal care beds, antepartum beds and postpartum beds. The design bed capacity does not include labor/delivery/recovery (LDR) beds, newborn nursery bassinets, or recovery beds.

(B) The maximum design bed capacity includes beds that comply with the requirements in §133.163 of this title even if the beds are unoccupied or the space is used for other purposes such as offices or storage rooms, provided such rooms can readily be returned to patient use. All required support and service areas must be maintained in place. For example, the removal of a nurse station in an unused patient bedroom wing of 20 beds would effectively eliminate those 20 beds from the design capacity. Eliminating access to the medical gas outlets and nurse call would also remove bed(s) from the design capacity.

(C) The number of licensed beds in a multiple-occupancy room shall be determined by the design even if the number of beds actually placed in the room is less than the design capacity.

(2) A hospital shall submit a license fee for each design bed added as a result of adding a multiple-location hospital to its license. The fee is $39 per bed, regardless of the number of months remaining in the license period.

(3) A hospital shall submit an additional license fee with the Final Construction Approval form for each new design bed resulting from an approved construction project. The fee is $39 per bed, regardless of the number of months remaining in the license period. The hospital shall also submit an additional plan review fee if the construction cost increases to the next higher fee schedule according to subsection (c)(4) of this section.

(4) A hospital will not receive a refund of previously submitted fees should the hospital's design capacity decrease as a result of an approved construction project.

(c) Plan review fees. This subsection outlines the fees which must accompany the application for plan review and all proposed plans and specifications covering the construction of new buildings or alterations to existing buildings which must be submitted for review and approval by the department in accordance with §133.167 of this title (relating to Preparation, Submittal, Review and Approval of Plans, and Retention of Records).

(1) Construction plans will not be reviewed or approved until the required fee and an application for plan review are received by the department.

(2) Plan review fees are based upon the estimated construction project costs which are the total expenditures required for a proposed project from initiation to completion, including at least the following items.

(A) Construction project costs shall include expenditures for physical assets such as:

(i) site acquisition;

(ii) soil tests and site preparation;

(iii) construction and improvements required as a result of the project;

(iv) building, structure, or office space acquisition;

(v) renovation;

(vi) fixed equipment; and

(vii) energy provisions and alternatives.

(B) Construction project costs shall include expenditures for professional services including:

(i) planning consultants;

(ii) architectural fees;

(iii) fees for cost estimation;

(iv) legal fees;

(v) management fees; and

(vi) feasibility study.

(C) Construction project costs shall include expenditures or costs associated with financing, excluding long-term interest, but including:

(i) financial advisor;

(ii) fund-raising expenses;

(iii) lender's or investment banker's fee; and

(iv) interest on interim financing.

(D) Construction project costs shall include expenditure allowances for contingencies including:

(i) inflation;

(ii) inaccurate estimates;

(iii) unforeseen fluctuations in the money market; and

(iv) other unforeseen expenditures.

(3) Regarding purchases, donations, gifts, transfers, and other comparable arrangements whereby the acquisition is to be made for no consideration or at less than the fair market value, the project cost shall be determined by the fair market value of the item to be acquired as a result of the purchase, donation, gift, transfer, or other comparable arrangement.

(4) The plan review fee schedule based on cost of construction is:

(A) $100,000 or less--$300;

(B) $100,001 to $600,000--$850;

(C) $600,001 to $2,000,000--$2,000;

(D) $2,000,001 to $5,000,000--$3,000;

(E) $5,000,001 to $10,000,000--$4,000; and

(F) $10,000,001 and over--$5,000.

(5) If an estimated construction cost cannot be established, the estimated cost shall be based on $225 per square foot. No construction project shall be increased in size, scope, or cost unless the appropriate fees are submitted with the proposed changes.

(d) Construction inspection fees. A fee of $500 and an application for construction inspection for each inspection shall be submitted to the department at least three weeks prior to the anticipated inspection date. Construction inspections will not be conducted until all required fees are received by the department. If additional construction inspections of the proposed project are requested by the hospital, the appropriate additional fees shall be submitted prior to any inspections conducted by the staff of the department. When follow-up construction inspections are performed to verify plans of correction, the fee shall be submitted upon completion of the inspection.

(e) Cooperative agreement application fee. The application fee for a cooperative agreement is $10,000. The application fee shall be submitted with an application for a cooperative agreement and other documents in accordance with §133.62 of this title (relating to Cooperative Agreements).

(f) Subscription and convenience fee. The department is authorized to collect subscription and convenience fees, in amounts determined by the TexasOnline Authority, to recover costs associated with application and renewal application processing through TexasOnline, in accordance with Texas Government Code, §2054.111. At each renewal application, in addition to the license fee, there shall be a $20 TexasOnline subscription fee.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

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SUBCHAPTER C. OPERATIONAL REQUIREMENTS

25 TAC §§133.41 - 133.48

STATUTORY AUTHORITY

The repeals are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

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25 TAC §§133.41 - 133.48

STATUTORY AUTHORITY

The new sections are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

§133.41. Hospital Functions and Services.

(a) Anesthesia services. If the hospital furnishes anesthesia services, these services shall be provided in a well-organized manner under the direction of a qualified physician in accordance with the Medical Practice Act and the Nursing Practice Act. The hospital is responsible for and shall document all anesthesia services administered in the hospital.

(1) Organization and staffing. The organization of anesthesia services shall be appropriate to the scope of the services offered. Only personnel who have been approved by the facility to provide anesthesia services shall administer anesthesia. All approvals or delegations of anesthesia services as authorized by law shall be documented and include the training, experience, and qualifications of the person who provided the service.

(2) Delivery of services. Anesthesia services shall be consistent with needs and resources. Policies on anesthesia procedure shall include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies shall ensure that the following are provided for each patient.

(A) A pre-anesthesia evaluation by an individual qualified to administer anesthesia under paragraph (1) of this subsection shall be performed within 48 hours prior to surgery.

(B) An intraoperative anesthesia record shall be provided. The record shall include any complications or problems occurring during the anesthesia including time, description of symptoms, review of affected systems, and treatments rendered. The record shall correlate with the controlled substance administration record.

(C) A post-anesthesia follow-up report shall be written by the person administering the anesthesia before transferring the patient from the post-anesthesia care unit and shall include evaluation for recovery from anesthesia, level of activity, respiration, blood pressure, level of consciousness, and patient's oxygen saturation level.

(i) With respect to inpatients, a post-anesthesia evaluation for proper anesthesia recovery shall be performed after transfer from the post-anesthesia care unit and within 48 hours after surgery by the person administering the anesthesia, registered nurse (RN), or physician in accordance with policies and procedures approved by the medical staff and using criteria written in the medical staff bylaws for postoperative monitoring of anesthesia.

(ii) With respect to outpatients, immediately prior to discharge, a post-anesthesia evaluation for proper anesthesia recovery shall be performed by the person administering the anesthesia, RN, or physician in accordance with policies and procedures approved by the medical staff and using criteria written in the medical staff bylaws for postoperative monitoring of anesthesia.

(b) Chemical dependency services.

(1) Chemical dependency unit. A hospital may not admit patients to a chemical dependency services unit unless the unit is approved by the Department of State Health Services (department) as meeting the requirements of §133.163(q) of this title (relating to Spatial Requirements for New Construction).

(2) Admission criteria. A hospital providing chemical dependency services shall have written admission criteria that are applied uniformly to all patients who are admitted to the chemical dependency unit.

(A) The hospital's admission criteria shall include procedures to prevent the admission of minors for a condition which is not generally recognized as responsive to treatment in an inpatient setting for chemical dependency services.

(i) The following conditions are not generally recognized as responsive to treatment in a treatment facility for chemical dependency unless the minor to be admitted is qualified because of other disabilities, such as:

(I) cognitive disabilities due to mental retardation;

(II) learning disabilities; or

(III) psychiatric disorders.

(ii) A minor may be qualified for admission based on other disabilities which would be responsive to chemical dependency services.

(iii) A minor patient shall be separated from adult patients.

(B) The hospital shall have a preadmission examination procedure under which each patient's condition and medical history are reviewed by a member of the medical staff to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(C) A voluntarily admitted patient shall sign an admission consent form prior to admission to a chemical dependency unit which includes verification that the patient has been informed of the services to be provided and the estimated charges.

(3) Compliance. A hospital providing chemical dependency services in an identifiable unit within the hospital shall comply with Chapter 448, Subchapter B of this title (relating to Standard of Care Applicable to All Providers).

(c) Comprehensive medical rehabilitation services.

(1) Rehabilitation units. A hospital may not admit patients to a comprehensive medical rehabilitation services unit unless the unit is approved by the department as meeting the requirements of §133.163(z) of this title.

(2) Equipment and space. The hospital shall have the necessary equipment and sufficient space to implement the treatment plan described in paragraph (7)(C) of this subsection and allow for adequate care. Necessary equipment is all equipment necessary to comply with all parts of the written treatment plan. The equipment shall be on-site or available through an arrangement with another provider. Sufficient space is the physical area of a hospital which in the aggregate, constitutes the total amount of the space necessary to comply with the written treatment plan.

(3) Emergency requirements. Emergency personnel, equipment, supplies and medications for hospitals providing comprehensive medical rehabilitation services shall be as follows.

(A) A hospital that provides comprehensive medical rehabilitation services shall have emergency equipment, supplies, medications, and designated personnel assigned for providing emergency care to patients and visitors.

(B) The emergency equipment, supplies, and medications shall be properly maintained and immediately accessible to all areas of the hospital. The emergency equipment shall be periodically tested according to the policy adopted, implemented and enforced by the hospital.

(C) At a minimum, the emergency equipment and supplies shall include those specified in subsection (e)(4) of this section.

(D) The personnel providing emergency care in accordance with this subsection shall be staffed for 24-hour coverage and accessible to all patients receiving comprehensive medical rehabilitation services. At least one person who is qualified by training to perform advanced cardiac life support and administer emergency drugs shall be on duty each shift.

(E) All direct patient care licensed personnel shall maintain current certification in cardiopulmonary resuscitation (CPR).

(4) Medications. A rehabilitation hospital's governing body shall adopt, implement and enforce policies and procedures that require all medications to be administered by licensed nurses, physicians, or other licensed professionals authorized by law to administer medications.

(5) Organization and Staffing.

(A) A hospital providing comprehensive medical rehabilitation services shall be organized and staffed to ensure the health and safety of the patients.

(i) All provided services shall be consistent with accepted professional standards and practice.

(ii) The organization of the services shall be appropriate to the scope of the services offered.

(iii) The hospital shall adopt, implement and enforce written patient care policies that govern the services it furnishes.

(B) The provision of comprehensive medical rehabilitation services in a hospital shall be under the medical supervision of a physician who is on duty and available, or who is on-call 24 hours each day.

(C) A hospital providing comprehensive medical rehabilitation services shall have a medical director or clinical director who supervises and administers the provision of comprehensive medical rehabilitation services.

(i) The medical director or clinical director shall be a physician who is board certified or eligible for board certification in physical medicine and rehabilitation, orthopedics, neurology, neurosurgery, internal medicine, or rheumatology as appropriate for the rehabilitation program.

(ii) The medical director or clinical director shall be qualified by training or at least two years training and experience to serve as medical director or clinical director. A person is qualified under this subsection if the person has training and experience in the treatment of rehabilitation patients in a rehabilitation setting.

(6) Admission criteria. A hospital providing comprehensive medical rehabilitation services shall have written admission criteria that are applied uniformly to all patients who are admitted to the comprehensive medical rehabilitation unit.

(A) The hospital's admission criteria shall include procedures to prevent the admission of a minor for a condition which is not generally recognized as responsive to treatment in an inpatient setting for comprehensive medical rehabilitation services.

(i) The following conditions are not generally recognized as responsive to treatment in an inpatient setting for comprehensive medical rehabilitation services unless the minor to be admitted is qualified because of other disabilities, such as:

(I) cognitive disabilities due to mental retardation;

(II) learning disabilities; or

(III) psychiatric disorders.

(ii) A minor may be qualified for admission based on other disabilities which would be responsive to comprehensive medical rehabilitation services.

(B) The hospital shall have a preadmission examination procedure under which each patient's condition and medical history are reviewed by a member of the medical staff to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(7) Care and services.

(A) A hospital providing comprehensive medical rehabilitation services shall use a coordinated interdisciplinary team which is directed by a physician and which works in collaboration to develop and implement the patient's treatment plan.

(i) The interdisciplinary team for comprehensive medical rehabilitation services shall have available to it, at the hospital at which the services are provided or by contract, members of the following professions as necessary to meet the treatment needs of the patient:

(I) physical therapy;

(II) occupational therapy;

(III) speech-language pathology;

(IV) therapeutic recreation;

(V) social services and case management;

(VI) dietetics;

(VII) psychology;

(VIII) respiratory therapy;

(IX) rehabilitative nursing;

(X) certified orthotics;

(XI) certified prosthetics;

(XII) pharmaceutical care; and

(XIII) in the case of a minor patient, persons who have specialized education and training in emotional, mental health, or chemical dependency problems, as well as the treatment of minors.

(ii) The coordinated interdisciplinary team approach used in the rehabilitation of each patient shall be documented by periodic entries made in the patient's medical record to denote:

(I) the patient's status in relationship to goal attainment; and

(II) that team conferences are held at least every two weeks to determine the appropriateness of treatment.

(B) An initial assessment and preliminary treatment plan shall be performed or established by the physician within 24 hours of admission.

(C) The physician in coordination with the interdisciplinary team shall establish a written treatment plan for the patient within seven working days of the date of admission.

(i) Comprehensive medical rehabilitation services shall be provided in accordance with the written treatment plan.

(ii) The treatment provided under the written treatment plan shall be provided by staff who are qualified to provide services under state law. The hospital shall establish written qualifications for services provided by each discipline for which there is no applicable state statute for professional licensure or certification.

(iii) Services provided under the written treatment plan shall be given in accordance with the orders of physicians, dentists, podiatrists or practitioners who are authorized by the governing body, hospital administration, and medical staff to order the services, and the orders shall be incorporated in the patient's record.

(iv) The written treatment plan shall delineate anticipated goals and specify the type, amount, frequency, and anticipated duration of service to be provided.

(v) Within 10 working days after the date of admission, the written treatment plan shall be provided. It shall be in the person's primary language, if practicable. What is or would have been practicable shall be determined by the facts and circumstances of each case. The written treatment plan shall be provided to:

(I) the patient;

(II) a person designated by the patient; and

(III) upon request, a family member, guardian, or individual who has demonstrated on a routine basis responsibility

and participation in the patient's care or treatment, but only with the patient's consent unless such consent is not required by law.

(vi) The written treatment plan shall be reviewed by the interdisciplinary team at least every two weeks.

(vii) The written treatment plan shall be revised by the interdisciplinary team if a comprehensive reassessment of the patient's status or the results of a patient case review conference indicates the need for revision.

(viii) The revision shall be incorporated into the patient's record within seven working days after the revision.

(ix) The revised treatment plan shall be reduced to writing in the person's primary language, if practicable, and provided to:

(I) the patient;

(II) a person designated by the patient; and

(III) upon request, a family member, guardian, or individual who has demonstrated on a routine basis responsibility and participation in the patient's care or treatment, but only with the patient's consent unless such consent is not required by law.

(8) Discharge and continuing care plan. The patient's interdisciplinary team shall prepare a written continuing care plan that addresses the patient's needs for care after discharge.

(A) The continuing care plan for the patient shall include recommendations for treatment and care and information about the availability of resources for treatment or care.

(B) If the patient's interdisciplinary team deems it impracticable to provide a written continuing care plan prior to discharge, the patient's interdisciplinary team shall provide the written continuing care plan to the patient within two working days after the date of discharge.

(C) Prior to discharge or within two working days after the date of discharge, the written continuing care plan shall be provided in the person's primary language, if practicable, to:

(i) the patient;

(ii) a person designated by the patient; and

(iii) upon request, to a family member, guardian, or individual who has demonstrated on a routine basis responsibility and participation in the patient's care or treatment, but only with the patient's consent unless such consent is not required by law.

(d) Dietary services. The hospital shall have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company or an arrangement with another hospital may meet this requirement if the company or other hospital has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company or other hospital maintains at least the minimum requirements specified in this section, and provides for the frequent and systematic liaison with the hospital medical staff for recommendations of dietetic policies affecting patient treatment. The hospital shall ensure that there are sufficient personnel to respond to the dietary needs of the patient population being served.

(1) Organization.

(A) The hospital shall have a full-time employee who is qualified by experience or training to serve as director of the food and dietetic service, and be responsible for the daily management of the dietary services.

(B) There shall be a qualified dietitian who works full-time, part-time, or on a consultant basis. If by consultation, such services shall occur at least once per month for not less than eight hours. The dietitian shall:

(i) be currently licensed under the laws of this state to use the titles of licensed dietitian or provisional licensed dietitian, or be a registered dietitian;

(ii) maintain standards for professional practice;

(iii) supervise the nutritional aspects of patient care;

(iv) make an assessment of the nutritional status and adequacy of nutritional regimen, as appropriate;

(v) provide diet counseling and teaching, as appropriate;

(vi) document nutritional status and pertinent information in patient medical records, as appropriate;

(vii) approve menus; and

(viii) approve menu substitutions.

(C) There shall be administrative and technical personnel competent in their respective duties. The administrative and technical personnel shall:

(i) participate in established departmental or hospital training pertinent to assigned duties;

(ii) conform to food handling techniques in accordance with paragraph (2)(E)(viii) of this subsection;

(iii) adhere to clearly defined work schedules and assignment sheets; and

(iv) comply with position descriptions which are job specific.

(2) Director. The director shall:

(A) comply with a position description which is job specific;

(B) clearly delineate responsibility and authority;

(C) participate in conferences with administration and department heads;

(D) establish, implement, and enforce policies and procedures for the overall operational components of the department to include, but not be limited to:

(i) quality assessment and performance improvement program;

(ii) frequency of meals served;

(iii) nonroutine occurrences; and

(iv) identification of patient trays; and

(E) maintain authority and responsibility for the following, but not be limited to:

(i) orientation and training;

(ii) performance evaluations;

(iii) work assignments;

(iv) supervision of work and food handling techniques;

(v) procurement of food, paper, chemical, and other supplies, to include implementation of first-in first-out rotation system for all food items;

(vi) ensuring there is a four-day food supply on hand at all times;

(vii) menu planning; and

(viii) ensuring compliance with §§229.161 - 229.171 of this title (relating to Texas Food Establishments).

(3) Diets. Menus shall meet the needs of the patients.

(A) Therapeutic diets shall be prescribed by the physician(s) responsible for the care of the patients. The dietary department of the hospital shall:

(i) establish procedures for the processing of therapeutic diets to include, but not be limited to:

(I) accurate patient identification;

(II) transcription from nursing to dietary services;

(III) diet planning by a dietitian;

(IV) regular review and updating of diet when necessary; and

(V) written and verbal instruction to patient and family. It shall be in the patient's primary language, if practicable, prior to discharge. What is or would have been practicable shall be determined by the facts and circumstances of each case;

(ii) ensure that therapeutic diets are planned in writing by a qualified dietitian;

(iii) ensure that menu substitutions are approved by a qualified dietitian;

(iv) document pertinent information about the patient's response to a therapeutic diet in the medical record; and

(v) evaluate therapeutic diets for nutritional adequacy.

(B) Nutritional needs shall be met in accordance with recognized dietary practices and in accordance with orders of the physician(s) or appropriately credentialed practitioner(s) responsible for the care of the patients. The following requirements shall be met.

(i) Menus shall provide a sufficient variety of foods served in adequate amounts at each meal according to the guidance provided in the Recommended Dietary Allowances (RDA), as published by the Food and Nutrition Board, Commission on Life Sciences, National Research Council, Tenth edition, 1989, which may be obtained by writing the National Academies Press, 500 Fifth Street, NW Lockbox 285, Washington, D.C. 20055, telephone (888) 624-8373.

(ii) A maximum of 15 hours shall not be exceeded between the last meal of the day (i.e. supper) and the breakfast meal, unless a substantial snack is provided. The hospital shall adopt, implement, and enforce a policy on the definition of "substantial" to meet each patient's varied nutritional needs.

(C) A current therapeutic diet manual approved by the dietitian and medical staff shall be readily available to all medical, nursing, and food service personnel. The therapeutic manual shall:

(i) be revised as needed, not to exceed 5 years;

(ii) be appropriate for the diets routinely ordered in the hospital;

(iii) have standards in compliance with the RDA;

(iv) contain specific diets which are not in compliance with RDA; and

(v) be used as a guide for ordering and serving diets.

(e) Emergency services. All licensed hospital locations, including multiple-location sites, shall have an emergency suite that complies with §133.161(a)(1)(A) of this title (relating to Requirements for Buildings in Which Existing Licensed Hospitals are Located) or §133.163(f) of this title, and the following.

(1) Organization. The organization of the emergency services shall be appropriate to the scope of the services offered.

(A) The services shall be organized under the direction of a qualified member of the medical staff who is the medical director or clinical director.

(B) The services shall be integrated with other departments of the hospital.

(C) The policies and procedures governing medical care provided in the emergency suite shall be established by and shall be a continuing responsibility of the medical staff.

(D) Medical records indicating patient identification, complaint, physician, nurse, time admitted to the emergency suite, treatment, time discharged, and disposition shall be maintained for all emergency patients.

(2) Personnel.

(A) There shall be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the hospital.

(B) Except for comprehensive medical rehabilitation hospitals and pediatric and adolescent hospitals that generally provide care that is not administered for or in expectation of compensation:

(i) there shall be on duty and available at all times at least one person qualified as determined by the medical staff to initiate immediate appropriate lifesaving measures; and

(ii) in general hospitals where the emergency treatment area is not contiguous with other areas of the hospital that maintain 24 hour staffing by qualified staff (including but not limited to separation by one or more floors in multiple-occupancy buildings), qualified personnel must be physically present in the emergency treatment area at all times.

(C) Except for comprehensive medical rehabilitation hospitals and pediatric and adolescent hospitals that generally provide care that is not administered for or in expectation of compensation, the hospital shall provide that one or more physicians shall be available at all times for emergencies, as follows.

(i) General hospitals, except for hospitals designated as critical access hospitals (CAHs) by the Centers for Medicare & Medicaid Services (CMS), located in counties with a population of 100,000 or more shall have a physician qualified to provide emergency medical care on duty in the emergency treatment area at all times.

(ii) Special hospitals, hospitals designated as CAHs by the CMS, and general hospitals located in counties with a population of less than 100,000 shall have a physician on-call and able to respond in person, or by radio or telephone within 30 minutes.

(D) Schedules, names, and telephone numbers of all physicians and others on emergency call duty, including alternates,

shall be maintained. Schedules shall be retained for no less than one year.

(3) Supplies and equipment. Adequate age appropriate supplies and equipment shall be available and in readiness for use. Equipment and supplies shall be available for the administration of intravenous medications as well as facilities for the control of bleeding and emergency splinting of fractures. Provision shall be made for the storage of blood and blood products as needed. The emergency equipment shall be periodically tested according to the policy adopted, implemented and enforced by the hospital.

(4) Required emergency equipment. At a minimum, the age appropriate emergency equipment and supplies shall include the following:

(A) emergency call system;

(B) oxygen;

(C) mechanical ventilatory assistance equipment, including airways, manual breathing bag, and mask;

(D) cardiac defibrillator;

(E) cardiac monitoring equipment;

(F) laryngoscopes and endotracheal tubes;

(G) suction equipment;

(H) emergency drugs and supplies specified by the medical staff;

(I) stabilization devices for cervical injuries;

(J) blood pressure monitoring equipment; and

(K) pulse oximeter or similar medical device to measure blood oxygenation.

(5) Participation in local emergency medical service (EMS) system.

(A) General hospitals shall participate in the local EMS system, based on the hospital's capabilities and capacity, and the locale's existing EMS plan and protocols.

(B) The provisions of subparagraph (A) of this paragraph do not apply to a comprehensive medical rehabilitation hospital or a pediatric and adolescent hospital that generally provides care that is not administered for or in expectation of compensation.

(6) Emergency services for survivors of sexual assault.

(A) The hospital must develop, implement and enforce policies and procedures to ensure that a sexual assault survivor who presents to the hospital following a sexual assault is:

(i) provided the care specified under subparagraph (B) of this paragraph; or

(ii) stabilized and transferred to a health care facility designated in a community-wide plan as the health care facility for treating sexual assault survivors, where the survivor will receive the care specified under subparagraph (B) of this paragraph.

(B) A hospital which provides care to a sexual assault survivor shall provide the survivor with the following:

(i) a private area, if available, to wait and to speak with the appropriate medical, legal and sexual assault crisis center staff or volunteers until a physician, nurse, or other qualified medical personnel is able to treat the survivor;

(ii) a private treatment room, if available;

(iii) a forensic medical examination in accordance with Government Code, Chapter 420, Subchapter B, if the examination has been approved by a law enforcement agency;

(iv) access to a sexual assault program advocate, if available, as provided by Code of Criminal Procedure, Article 56.045;

(v) the department's standard Information Form for Sexual Assault Survivors, which may be obtained through the department's website or by contacting the hospital licensing program at (512) 834-6648;

(vi) the name and telephone number of the nearest sexual assault crisis center; and

(vii) if indicated, access to appropriate prophylaxis for exposure to sexually transmitted infections.

(C) Upon request, the hospital shall submit to the department their plan for the provision of service to sexual assault survivors. The plan must describe how the hospital will ensure that the services required under subparagraph (B) of this paragraph will be provided.

(i) The hospital shall submit the plan by the 60th day after the department makes the request.

(ii) The department will approve or reject the plan not later than 120th day following the submission of the plan.

(iii) If the department is not able to approve the plan, the department will return the plan to the hospital and will identify the specific provisions with which the hospital's plan failed to comply.

(iv) The hospital shall correct and resubmit the plan to the department for approval not later than the 90th day after the plan is returned to the hospital.

(f) Governing body.

(1) Legal responsibility. There shall be a governing body responsible for the organization, management, control, and operation of the hospital, including appointment of the medical staff. For hospitals owned and operated by an individual or by partners, the individual or partners shall be considered the governing body.

(2) Organization. The governing body shall be formally organized in accordance with a written constitution and bylaws which clearly set forth the organizational structure and responsibilities.

(3) Meeting records. Records of governing body meetings shall be maintained.

(4) Responsibilities relating to the medical staff.

(A) The governing body shall ensure that the medical staff has current bylaws, rules, and regulations which are implemented and enforced.

(B) The governing body shall approve medical staff bylaws and other medical staff rules and regulations.

(C) The governing body shall determine, in accordance with state law and with the advice of the medical staff, which categories of practitioners are eligible candidates for appointment to the medical staff.

(i) In considering applications for medical staff membership and privileges or the renewal, modification, or revocation of medical staff membership and privileges, the governing body must ensure that each physician, podiatrist, and dentist is afforded procedural due process.

(I) If a hospital's credentials committee has failed to take action on a completed application as required by subclause (VIII) of this clause, or a physician, podiatrist, or dentist is subject to a professional review action that may adversely affect his medical staff membership or privileges, and the physician, podiatrist, or dentist believes that mediation of the dispute is desirable, the physician, podiatrist, or dentist may require the hospital to participate in mediation as provided in Civil Practice and Remedies Code (CPRC), Chapter 154. The mediation shall be conducted by a person meeting the qualifications required by CPRC §154.052 and within a reasonable period of time.

(II) Subclause (I) of this clause does not authorize a cause of action by a physician, podiatrist, or dentist against the hospital other than an action to require a hospital to participate in mediation.

(III) An applicant for medical staff membership or privileges may not be denied membership or privileges on any ground that is otherwise prohibited by law.

(IV) A hospital's bylaw requirements for staff privileges may require a physician, podiatrist, or dentist to document the person's current clinical competency and professional training and experience in the medical procedures for which privileges are requested.

(V) In granting or refusing medical staff membership or privileges, a hospital may not differentiate on the basis of the academic medical degree held by a physician.

(VI) Graduate medical education may be used as a standard or qualification for medical staff membership or privileges for a physician, provided that equal recognition is given to training programs accredited by the Accreditation Council for Graduate Medical Education and by the American Osteopathic Association.

(VII) Board certification may be used as a standard or qualification for medical staff membership or privileges for a physician, provided that equal recognition is given to certification programs approved by the American Board of Medical Specialties and the Bureau of Osteopathic Specialists.

(VIII) A hospital's credentials committee shall act expeditiously and without unnecessary delay when a licensed physician, podiatrist, or dentist submits a completed application for medical staff membership or privileges. The hospital's credentials committee shall take action on the completed application not later than the 90th day after the date on which the application is received. The governing body of the hospital shall take final action on the application for medical staff membership or privileges not later than the 60th day after the date on which the recommendation of the credentials committee is received. The hospital must notify the applicant in writing of the hospital's final action, including a reason for denial or restriction of privileges, not later than the 20th day after the date on which final action is taken.

(ii) The governing body is authorized to adopt, implement and enforce policies concerning the granting of clinical privileges to advanced practice nurses and physician assistants, including policies relating to the application process, reasonable qualifications for privileges, and the process for renewal, modification, or revocation of privileges.

(I) If the governing body of a hospital has adopted, implemented and enforced a policy of granting clinical privileges to advanced practice nurses or physician assistants, an individual advanced practice nurse or physician assistant who qualifies for privileges under that policy shall be entitled to certain procedural rights to provide fairness of process, as determined by the governing body of the hospital, when an application for privileges is submitted to the hospital. At a minimum, any policy adopted shall specify a reasonable period for the processing and consideration of the application and shall provide for written notification to the applicant of any final action on the application by the hospital, including any reason for denial or restriction of the privileges requested.

(II) If an advanced practice nurse or physician assistant has been granted clinical privileges by a hospital, the hospital may not modify or revoke those privileges without providing certain procedural rights to provide fairness of process, as determined by the governing body of the hospital, to the advanced practice nurse or physician assistant. At a minimum, the hospital shall provide the advanced practice nurse or physician assistant written reasons for the modification or revocation of privileges and a mechanism for appeal to the appropriate committee or body within the hospital, as determined by the governing body of the hospital.

(III) If a hospital extends clinical privileges to an advanced practice nurse or physician assistant conditioned on the advanced practice nurse or physician assistant having a sponsoring or collaborating relationship with a physician and that relationship ceases to exist, the advanced practice nurse or physician assistant and the physician shall provide written notification to the hospital that the relationship no longer exists. Once the hospital receives such notice from an advanced practice nurse or physician assistant and the physician, the hospital shall be deemed to have met its obligations under this section by notifying the advanced practice nurse or physician assistant in writing that the advanced practice nurse's or physician assistant's clinical privileges no longer exist at that hospital.

(IV) Nothing in this clause shall be construed as modifying Subtitle B, Title 3, Occupations Code, Chapter 204 or 301, or any other law relating to the scope of practice of physicians, advanced practice nurses, or physician assistants.

(V) This clause does not apply to an employer-employee relationship between an advanced practice nurse or physician assistant and a hospital.

(D) The governing body shall ensure that the hospital complies with the requirements concerning physician communication and contracts as set out in Health and Safety Code (HSC), §241.1015 (Physician Communication and Contracts); and

(E) The governing body shall ensure the hospital complies with the requirements for reporting to the Texas Medical Board the results and circumstances of any professional review action in accordance with the Medical Practice Act, Texas Occupations Code, §160.002 and §160.003.

(F) The governing body shall be responsible for and ensure that any policies and procedures adopted by the governing body to implement the requirements of this chapter shall be implemented and enforced.

(5) Hospital administration. The governing body shall appoint a chief executive officer or administrator who is responsible for managing the hospital.

(6) Patient care. In accordance with hospital policy adopted, implemented and enforced, the governing body shall ensure that:

(A) every patient is under the care of:

(i) a physician. This provision is not to be construed to limit the authority of a physician to delegate tasks to other qualified

health care personnel to the extent recognized under state law or the state's regulatory mechanism;

(ii) a dentist who is legally authorized to practice dentistry by the state and who is acting within the scope of his or her license; or

(iii) a podiatrist, but only with respect to functions which he or she is legally authorized by the state to perform.

(B) patients are admitted to the hospital only by members of the medical staff who have been granted admitting privileges; and

(C) a physician is on duty or on-call at all times.

(7) Services. The governing body shall be responsible for all services furnished in the hospital, whether furnished directly or under contract. The governing body shall ensure that services are provided in a safe and effective manner that permits the hospital to comply with all applicable rules and standards.

(g) Infection control. The hospital shall provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There shall be an active program for the prevention, control, and surveillance of infections and communicable diseases.

(1) Organization and policies. A person shall be designated as infection control professional. The hospital shall ensure that policies governing prevention, control and surveillance of infections and communicable diseases are developed, implemented and enforced.

(A) There shall be a system for identifying, reporting, investigating, and controlling health care associated infections and communicable diseases between patients and personnel.

(B) The infection control professional shall maintain a log of all reportable diseases and health care associated infections designated as epidemiologically significant according to the hospital's infection control policies.

(C) A written policy shall be adopted, implemented and enforced for reporting all reportable diseases to the local health authority and the Infectious Disease Surveillance and Epidemiology Branch, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756-3199, in accordance with Chapter 97 of this title (relating to Communicable Diseases).

(D) The infection control program shall include active participation by the pharmacist.

(2) Responsibilities of the chief executive officer (CEO), medical staff, and chief nursing officer (CNO). The CEO, the medical staff, and the CNO shall be responsible for the following.

(A) The hospital-wide quality assessment and performance improvement program and training programs shall address problems identified by the infection control professional.

(B) Successful corrective action plans in affected problem areas shall be implemented.

(3) Universal precautions. The hospital shall adopt, implement, and enforce a written policy to monitor compliance of the hospital and its personnel and medical staff with universal precautions in accordance with HSC Chapter 85, Acquired Immune Deficiency Syndrome and Human Immunodeficiency Virus Infection.

(h) Laboratory services. The hospital shall maintain directly, or have available adequate laboratory services to meet the needs of its patients.

(1) Hospital laboratory services. A hospital that provides laboratory services shall comply with the Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988), in accordance with the requirements specified in 42 Code of Federal Regulations (CFR), §§493.1 - 493.1780. CLIA 1988 applies to all hospitals with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(2) Contracted laboratory services. The hospital shall ensure that all laboratory services provided to its patients through a contractual agreement are performed in a facility certified in the appropriate specialties and subspecialties of service in accordance with the requirements specified in 42 CFR Part 493 to comply with CLIA 1988.

(3) Adequacy of laboratory services. The hospital shall ensure the following.

(A) Emergency laboratory services shall be available 24 hours a day.

(B) A written description of services provided shall be available to the medical staff.

(C) The laboratory shall make provision for proper receipt and reporting of tissue specimens.

(D) The medical staff and a pathologist shall determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examination.

(E) When blood and blood components are stored, there shall be written procedures readily available containing directions on how to maintain them within permissible temperatures and including instructions to be followed in the event of a power failure or other disruption of refrigeration. A label or tray with the recipient's first and last names and identification number, donor unit number and interpretation of compatibility, if performed, shall be attached securely to the blood container.

(F) The hospital shall establish a mechanism for ensuring that the patient's physician or other licensed health care professional is made aware of critical value lab results, as established by the medical staff, before or after the patient is discharged.

(4) Chemical hygiene. A hospital that provides laboratory services shall adopt, implement, and enforce written policies and procedures to manage, minimize, or eliminate the risks to laboratory personnel of exposure to potentially hazardous chemicals in the laboratory which may occur during the normal course of job performance.

(i) Linen and laundry services. The hospital shall provide sufficient clean linen to ensure the comfort of the patient.

(1) For purposes of this subsection, contaminated linen is linen which has been soiled with blood or other potentially infectious materials or may contain sharps. Other potentially infectious materials means:

(A) the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

(B) any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(C) Human Immunodeficiency Virus (HIV)-containing cell or tissue cultures, organ cultures, and HIV or Hepatitis B Virus

(HBV)-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

(2) The hospital, whether it operates its own laundry or uses commercial service, shall ensure the following.

(A) Employees of a hospital involved in transporting, processing, or otherwise handling clean or soiled linen shall be given initial and follow-up in-service training to ensure a safe product for patients and to safeguard employees in their work.

(B) Clean linen shall be handled, transported, and stored by methods that will ensure its cleanliness.

(C) All contaminated linen shall be placed and transported in bags or containers labeled or color-coded.

(D) Employees who have contact with contaminated linen shall wear gloves and other appropriate personal protective equipment.

(E) Contaminated linen shall be handled as little as possible and with a minimum of agitation. Contaminated linen shall not be sorted or rinsed in patient care areas.

(F) All contaminated linen shall be bagged or put into carts at the location where it was used.

(i) Bags containing contaminated linen shall be closed prior to transport to the laundry.

(ii) Whenever contaminated linen is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the linen shall be deposited and transported in bags that prevent leakage of fluids to the exterior.

(iii) All linen placed in chutes shall be bagged.

(iv) If chutes are not used to convey linen to a central receiving or sorting room, then adequate space shall be allocated on the various nursing units for holding the bagged contaminated linen.

(G) Linen shall be processed as follows:

(i) If hot water is used, linen shall be washed with detergent in water with a temperature of at least 71 degrees Centigrade (160 degrees Fahrenheit) for 25 minutes. Hot water requirements specified in Table 5 of §133.169(e) of this title (relating to Tables) shall be met.

(ii) If low-temperature (less than or equal to 70 degrees Centigrade) (158 degrees Fahrenheit) laundry cycles are used, chemicals suitable for low-temperature washing at proper use concentration shall be used.

(iii) Commercial dry cleaning of fabrics soiled with blood also renders these items free of the risk of pathogen transmission.

(H) Flammable liquids shall not be used to process laundry, but may be used for equipment maintenance.

(j) Medical record services. The hospital shall have a medical record service that has administrative responsibility for medical records. A medical record shall be maintained for every individual who presents to the hospital for evaluation or treatment.

(1) The organization of the medical record service shall be appropriate to the scope and complexity of the services performed. The hospital shall employ or contract with adequate personnel to ensure prompt completion, filing, and retrieval of records.

(2) The hospital shall have a system of coding and indexing medical records. The system shall allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(3) The hospital shall adopt, implement, and enforce a policy to ensure that the hospital complies with HSC, Chapter 241, Subchapter G (Disclosure of Health Care Information).

(4) The medical record shall contain information to justify admission and continued hospitalization, support the diagnosis, reflect significant changes in the patient's condition, and describe the patient's progress and response to medications and services. Medical records shall be accurately written, promptly completed, properly filed and retained, and accessible.

(5) Medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

(6) All orders (except verbal orders) must be dated, timed, and authenticated the next time the prescriber or another practitioner who is responsible for the care of the patient and has been credentialed by the medical staff and granted privileges which are consistent with the written orders provides care to the patient, assesses the patient, or documents information in the patient's medical record.

(7) All verbal orders must be dated, timed, and authenticated within 48 hours by the prescriber or another practitioner who is responsible for the care of the patient and has been credentialed by the medical staff and granted privileges which are consistent with the written orders.

(A) Use of signature stamps by physicians and other licensed practitioners credentialed by the medical staff may be allowed in hospitals when the signature stamp is authorized by the individual whose signature the stamp represents. The administrative offices of the hospital shall have on file a signed statement to the effect that he or she is the only one who has the stamp and uses it. The use of a signature stamp by any other person is prohibited.

(B) A list of computer codes and written signatures shall be readily available and shall be maintained under adequate safeguards.

(C) Signatures by facsimile shall be acceptable. If received on a thermal machine, the facsimile document shall be copied onto regular paper.

(8) Medical records (reports and printouts) shall be retained by the hospital in their original or legally reproduced form for a period of at least ten years. A legally reproduced form is a medical record retained in hard copy, microform (microfilm or microfiche), or other electronic medium. Films, scans, and other image records shall be retained for a period of at least five years. For retention purposes, medical records that shall be preserved for ten years include:

(A) identification data;

(B) the medical history of the patient;

(C) evidence of a physical examination, including a health history, performed no more than 30 days prior to admission or within 24 hours after admission. The medical history and physical examination shall be placed in the patient's medical record within 24 hours after admission.

(D) an updated medical record entry documenting an examination for any changes in the patient's condition when the medical history and physical examination are completed within 30 days before admission. This updated examination shall be completed and

documented in the patient's medical record within 24 hours after admission.

(E) admitting diagnosis;

(F) diagnostic and therapeutic orders;

(G) properly executed informed consent forms for procedures and treatments specified by the medical staff, or by federal or state laws if applicable, to require written patient consent;

(H) clinical observations, including the results of therapy and treatment, all orders, nursing notes, medication records, vital signs, and other information necessary to monitor the patient's condition;

(I) reports of procedures, tests, and their results, including laboratory, pathology, and radiology reports;

(J) results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient;

(K) discharge summary with outcome of hospitalization, disposition of care, and provisions for follow-up care; and

(L) final diagnosis with completion of medical records within 30 calendar days following discharge.

(9) If a patient was less than 18 years of age at the time he was last treated, the hospital may authorize the disposal of those medical records relating to the patient on or after the date of his 20th birthday or on or after the 10th anniversary of the date on which he was last treated, whichever date is later.

(10) The hospital shall not destroy medical records that relate to any matter that is involved in litigation if the hospital knows the litigation has not been finally resolved.

(11) If a licensed hospital should close, the hospital shall notify the department at the time of closure the disposition of the medical records, including the location of where the medical records will be stored and the identity and telephone number of the custodian of the records.

(k) Medical staff.

(1) The medical staff shall be composed of physicians and may also be composed of podiatrists, dentists and other practitioners appointed by the governing body.

(A) The medical staff shall periodically conduct appraisals of its members according to medical staff bylaws.

(B) The medical staff shall examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidate.

(2) The medical staff shall be well-organized and accountable to the governing body for the quality of the medical care provided to patients.

(A) The medical staff shall be organized in a manner approved by the governing body.

(B) If the medical staff has an executive committee, a majority of the members of the committee shall be doctors of medicine or osteopathy.

(C) Records of medical staff meetings shall be maintained.

(D) The responsibility for organization and conduct of the medical staff shall be assigned only to an individual physician.

(E) Each medical staff member shall sign a statement signifying they will abide by medical staff and hospital policies.

(3) The medical staff shall adopt, implement, and enforce bylaws, rules, and regulations to carry out its responsibilities. The bylaws shall:

(A) be approved by the governing body;

(B) include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, consultant);

(C) describe the organization of the medical staff;

(D) describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body;

(E) include criteria for determining the privileges to be granted and a procedure for applying the criteria to individuals requesting privileges; and

(F) include a requirement that a physical examination and medical history be done no more than 30 days before or 24 hours after an admission for each patient by a physician or other qualified practitioner who has been granted these privileges by the medical staff. The medical history and physical examination shall be placed in the patient's medical record within 24 hours after admission. When the medical history and physical examination are completed within the 30 days before admission, an updated examination for any changes in the patient's condition must be completed and documented in the patient's medical record within 24 hours after admission.

(l) Mental health services.

(1) Mental health services unit. A hospital may not admit patients to a mental health services unit unless the unit is approved by the department as meeting the requirements of §133.163(q) of this title.

(2) Admission criteria. A hospital providing mental health services shall have written admission criteria that are applied uniformly to all patients who are admitted to the service.

(A) The hospital's admission criteria shall include procedures to prevent the admission of minors for a condition which is not generally recognized as responsive to treatment in an inpatient setting for mental health services.

(i) The following conditions are not generally recognized as responsive to treatment in a hospital unless the minor to be admitted is qualified because of other disabilities, such as:

(I) cognitive disabilities due to mental retardation; or

(II) learning disabilities.

(ii) A minor may be qualified for admission based on other disabilities which would be responsive to mental health services.

(B) The medical record shall contain evidence that admission consent was given by the patient, the patient's legal guardian, or the managing conservator, if applicable.

(C) The hospital shall have a preadmission examination procedure under which each patient's condition and medical history are reviewed by a member of the medical staff to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(D) A voluntarily admitted patient shall sign an admission consent form prior to admission to a mental health unit which in-

cludes verification that the patient has been informed of the services to be provided and the estimated charges.

(3) Compliance. A hospital providing mental health services shall comply with the following rules administered by the department. The rules are:

(A) Chapter 411, Subchapter J of this title (relating to Standards of Care and Treatment in Psychiatric Hospitals);

(B) Chapter 404, Subchapter E of this title (relating to Rights of Persons Receiving Mental Health Services);

(C) Chapter 405, Subchapter E of this title (relating to Electroconvulsive Therapy (ECT));

(D) Chapter 414, Subchapter I of this title (relating to Consent to Treatment with Psychoactive Medication--Mental Health Services); and

(E) Chapter 415, Subchapter F of this title (relating to Interventions in Mental Health Programs).

(m) Mobile, transportable, and relocatable units. The hospital shall adopt, implement and enforce procedures which address the potential emergency needs for those inpatients who are taken to mobile units on the hospital's premises for diagnostic procedures or treatment.

(n) Nuclear medicine services. If the hospital provides nuclear medicine services, these services shall meet the needs of the patients in accordance with acceptable standards of practice and be licensed in accordance with §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material).

(1) Policies and procedures. Policies and procedures shall be adopted, implemented, and enforced which will describe the services nuclear medicine provides in the hospital and how employee and patient safety will be maintained.

(2) Organization and staffing. The organization of the nuclear medicine services shall be appropriate to the scope and complexity of the services offered.

(A) There shall be a medical director or clinical director who is a physician qualified in nuclear medicine.

(B) The qualifications, training, functions, and responsibilities of nuclear medicine personnel shall be specified by the medical director or clinical director and approved by the medical staff.

(3) Delivery of services. Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice and in accordance with §289.256 of this title.

(A) In-house preparation of radiopharmaceuticals shall be by, or under, the direct supervision of an appropriately trained licensed pharmacist or physician.

(B) There shall be proper storage and disposal of radioactive materials.

(C) If clinical laboratory tests are performed by the nuclear medicine services staff, the nuclear medicine staff shall comply with CLIA 1988 in accordance with the requirements specified in 42 CFR Part 493.

(D) Nuclear medicine workers shall be provided personnel monitoring dosimeters to measure their radiation exposure. Exposure reports and documentation shall be available for review.

(4) Equipment and supplies. Equipment and supplies shall be appropriate for the types of nuclear medicine services offered and shall be maintained for safe and efficient performance. The equipment shall be inspected, tested, and calibrated at least annually by qualified personnel.

(5) Records. The hospital shall maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(A) The physician approved by the medical staff to interpret diagnostic procedures shall sign and date the interpretations of these tests.

(B) The hospital shall maintain records of the receipt and disposition of radiopharmaceuticals until disposal is authorized by the department's Radiation Safety Licensing Branch in accordance with §289.256 of this title.

(C) Nuclear medicine services shall be ordered only by an individual whose scope of state licensure and whose defined staff privileges allow such referrals.

(o) Nursing services. The hospital shall have an organized nursing service that provides 24-hour nursing services as needed.

(1) Organization. The hospital shall have an organized nursing service that provides 24-hour nursing care. The nursing service shall be well-organized with a plan of administrative authority and delineation of responsibilities for patient care.

(A) Nursing services shall be under the administrative authority of a chief nursing officer (CNO) who shall be an RN and comply with one of the following:

(i) possess a master's degree in nursing;

(ii) possess a master's degree in health care administration or business administration;

(iii) possess a master's degree in a health-related field obtained through a curriculum that included courses in administration and management; or

(iv) be progressing under a written plan to obtain the nursing administration qualifications associated with a master's degree in nursing. The plan shall:

(I) describe efforts to obtain the knowledge associated with graduate education and to increase administrative and management skills and experience;

(II) include courses related to leadership, administration, management, performance improvement and theoretical approaches to delivering nursing care; and

(III) provide a time-line for accomplishing skills.

(B) The CNO in hospitals with 100 or fewer licensed beds and located in counties with a population of less than 50,000, or in hospitals that have been certified by the Centers for Medicare and Medicaid Services as critical access hospitals in accordance with the Code of Federal Regulations, Title 42, Volume 3, Part 485, Subpart F, §485.606(b), shall be exempted from the requirements in subparagraph (A)(i) - (iv) of this paragraph.

(C) The CNO shall be responsible for the operation of the services, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(D) The CNO shall report directly to the individual who has authority to represent the hospital and who is responsible for the operation of the hospital according to the policies and procedures of the hospital's governing board.

(E) The CNO shall participate with leadership from the governing body, medical staff, and clinical areas, in planning, promoting and conducting performance improvement activities.

(2) Staffing and delivery of care.

(A) The nursing services shall adopt, implement and enforce a procedure to verify that hospital nursing personnel for whom licensure is required have valid and current licensure.

(B) There shall be adequate numbers of RNs, licensed vocational nurses (LVNs), and other personnel to provide nursing care to all patients as needed.

(C) There shall be supervisory and staff personnel for each department or nursing unit to provide, when needed, the immediate availability of an RN to provide care for any patient.

(D) An RN shall be on duty in each building of a licensed hospital that contains at least one nursing unit where patients are present. The RN shall supervise and evaluate the nursing care for each patient and assign the nursing care to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

(E) The nursing staff shall develop and keep current a nursing plan of care for each patient which addresses the patient's needs.

(F) At a minimum, the following critical factors shall be considered in the determination of staffing levels:

(i) patient characteristics and number of patients for whom care is being provided, including number of admissions, discharges and transfers on a unit;

(ii) intensity of patient care being provided and variability of patient care across a nursing unit;

(iii) scope of services provided;

(iv) context within which care is provided, including architecture and geography of the environment, and the availability of technology; and

(v) nursing staff characteristics, including staff consistency and tenure, preparation and experience, and the number and competencies of clinical and nonclinical support staff the nurse must collaborate with or supervise.

(G) The hospital shall adopt, implement and enforce a written process for setting staffing levels that takes into account the critical factors specified in subparagraph (F) of this paragraph. The process shall include:

(i) establishing presumptive or initial staffing levels that are recalculated at least annually or as necessary;

(ii) setting staffing levels on a unit by unit basis or other bases appropriate to the hospital;

(iii) adjusting of staffing levels from shift to shift based on factors, such as, the intensity of patient care; and

(iv) reporting to the advisory committee, as referenced in subparagraph (H) of this paragraph, showing variance between desired and actual staffing levels, and an explanation for the variance. The reports shall be confidential and not subject to disclosure under Government Code, Chapter 552, and not subject to disclosure, discovery, subpoena or other means of legal compulsion for their release.

(H) The hospital shall designate an advisory committee established in accordance with Health and Safety Code (HSC), §§161.031 - 161.033, to be responsible for soliciting and receiving input from nurses on the development, ongoing monitoring, and evaluation of the staffing plan. As provided by HSC, §161.032, the hospital's records and review relating to evaluation of these outcomes and indicators are confidential and not subject to disclosure under Government Code, Chapter 552 and not subject to disclosure, discovery, subpoena or other means of legal compulsion for their release. The committee shall:

(i) have, as one-half of its members, registered nurses who are involved in direct patient care at least 50% of their work time;

(ii) include at least one representative from either infection control, quality assessment and program improvement or risk management; and

(iii) to the extent feasible, represent multiple areas of nursing practice.

(I) The hospital shall adopt, implement and enforce a written staffing plan.

(i) The staffing plan shall:

(I) be consistent with standards established by the Texas nurse licensing board and should be developed based upon a review of the codes of ethics developed by the nursing profession through national nursing organizations;

(II) utilize outcomes and nursing-sensitive indicators as an integral role in setting and evaluating the adequacy of the staffing plan. At least one from each of the following three types of outcomes shall be correlated to the adequacy of staffing:

(-a-) patient outcomes that are nursing-sensitive, such as, patient falls, adverse drug events, injuries to patients, skin breakdown, pneumonia, infection rates, upper gastrointestinal bleeding, shock, cardiac arrest, length of stay, or patient readmissions;

(-b-) operational outcomes, such as, work-related injury or illness, vacancy and turnover rates, nursing care hours per patient day, on-call use, or overtime rates; and

(-c-) substantiated patient complaints related to staffing levels;

(III) incorporate a process that facilitates the timely and effective identification of concerns about the adequacy of the staffing plan by the advisory committee established pursuant to subparagraph (H) of this paragraph. This process shall include:

(-a-) a prohibition on retaliation for reporting concerns;

(-b-) a requirement that nurses report concerns timely through appropriate channels within the hospital;

(-c-) orientation of nurses on how to report concerns and to whom;

(-d-) a process for providing feedback during the advisory committee meeting on how concerns are addressed by the advisory committee established under subparagraph (H) of this paragraph; and

(-e-) use of the nurse safe harbor peer review process pursuant to Occupations Code, §303.005;

(IV) include policies and procedures that require:

(-a-) orientation of nurses and other personnel who provide nursing care to all units to which they are assigned on either a temporary or permanent basis;

(-b-) that the orientation of nurses and other personnel and the competency to perform nursing services is documented in accordance with hospital policy;

(-c-) that nursing assignments be congruent with documented competency; and

(V) when utilized as a means for meeting staffing needs, include policy and procedures for mandatory overtime. The policy and procedures shall include:

(-a-) documentation of the basis and justification for mandatory overtime;

(-b-) an action plan for the reduction or elimination of the use of mandatory overtime to meet staffing needs;

(-c-) a process for monitoring and evaluating the use of mandatory overtime; and

(-d-) procedures for notifying nurses and other personnel who provide nursing care of the mandatory overtime policy. As used in this subsection, "mandatory overtime" means being required to work, other than on-call time, when not scheduled including beyond hours or days scheduled. Neither the length of the shift (whether 4, 8, 12, or 16 hours) nor the number of shifts scheduled to work (whether 4, 5, or 6 a week) is the determinative factor in defining mandatory overtime.

(ii) There shall be an annual evaluation of the nurse staffing plan, including an evaluation of the outcomes and nursing-sensitive indicators as set out in clause (i)(II) of this subparagraph. This evaluation shall be documented in the minutes of the advisory committee established under subparagraph (H) of this paragraph. Hospitals may determine whether this evaluation is done on a unit or facility level basis.

(iii) The staffing plan shall be retained for a period of two years.

(J) Nonemployee licensed nurses who are working in the hospital shall adhere to the policies and procedures of the hospital. The CNO shall provide for the adequate orientation, supervision, and evaluation of the clinical activities of nonemployee nursing personnel which occur within the responsibility of the nursing services.

(3) Drugs and biologicals. Drugs and biologicals shall be prepared and administered in accordance with federal and state laws, the orders of the individuals granted privileges by the medical staff, and accepted standards of practice.

(A) All drugs and biologicals shall be administered by, or under supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing rules, and in accordance with the approved medical staff policies and procedures.

(B) All orders for drugs and biologicals shall be in writing, dated, timed, and signed by the individual responsible for the care of the patient as specified under subsection (f)(6)(A) of this section. When telephone or verbal orders must be used, they shall be:

(i) accepted only by personnel who are authorized to do so by the medical staff policies and procedures, consistent with federal and state laws;

(ii) dated, timed, and authenticated within 48 hours by the prescriber or another practitioner who is responsible for the care of the patient and has been credentialed by the medical staff and granted privileges which are consistent with the written orders; and

(iii) used infrequently.

(C) There shall be a hospital procedure for immediately reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs to the attending physician and, if appropriate, to the hospital-wide quality assessment and performance improvement program.

(4) Blood transfusions.

(A) Transfusions shall be prescribed in accordance with hospital policy and administered in accordance with a written protocol for the administration of blood and blood components and the use of infusion devices and ancillary equipment.

(B) Personnel administering blood transfusions and intravenous medications shall have special training for this duty according to written, adopted, implemented and enforced hospital policy.

(C) Blood and blood components shall be transfused through a sterile, pyrogen-free transfusion set that has a filter designed to retain particles potentially harmful to the recipient.

(D) The patient must be observed during the transfusion and for an appropriate time thereafter for suspected adverse reactions.

(E) Pretransfusion and posttransfusion vital signs shall be recorded.

(F) When warming of blood is indicated, this shall be accomplished during its passage through the transfusion set. The warming system shall be equipped with a visible thermometer and may have an audible warning system. Blood shall not be warmed above 42 degrees Celsius.

(G) Drugs or medications, including those intended for intravenous use, shall not be added to blood or blood components. A 0.9% sodium chloride injection, United States Pharmacopeia, may be added to blood or blood components. Other solutions intended for intravenous use may be used in an administration set or added to blood or blood components under either of the following conditions:

(i) they have been approved for this use by the Federal Drug Administration; or

(ii) there is documentation available to show that addition to the component involved is safe and efficacious.

(H) There shall be a system for detection, reporting and evaluation of suspected complications of transfusion. Any adverse event experienced by a patient in association with a transfusion is to be regarded as a suspected transfusion complication. In the event of a suspected transfusion complication, the personnel attending the patient shall notify immediately a responsible physician and the transfusion service and document the complication in the patient's medical record. All suspected transfusion complications shall be evaluated promptly according to an established procedure.

(I) Following the transfusion, the blood transfusion record or a copy shall be made a part of the patient's medical record.

(5) Reporting and peer review of a vocational or registered nurse. A hospital shall adopt, implement, and enforce a policy to ensure that the hospital complies with the Occupations Code §§301.401 - 301.403, 301.405 and Chapter 303 (relating to Grounds for Reporting Nurse, Duty of Nurse to Report, Duty of Peer Review Committee to Report, Duty of Person Employing Nurse to Report, and Nursing Peer Review respectively), and with the rules adopted by the Board of Nurse Examiners in 22 TAC §217.16 (relating to Minor Incidents), §217.19 (relating to Incident-Based Nursing Peer Review), and §217.20 (relating to Safe Harbor Peer Review for Nurses).

(6) Policies and procedures related to workplace safety.

(A) The hospital shall adopt, implement and enforce policies and procedures related to the work environment for nurses which:

(i) improve workplace safety and reduce the risk of injury, occupational illness, and violence; and

(ii) increase the use of ergonomic principles and ergonomically designed devices to reduce injury and fatigue.

(B) The policies and procedures adopted under subparagraph (A) of this paragraph, at a minimum, must include:

(i) evaluating new products and technology that incorporate ergonomic principles;

(ii) educating nurses in the application of ergonomic practices;

(iii) conducting workplace audits to identify areas of risk of injury, occupational illness, or violence and recommending ways to reduce those risks;

(iv) controlling access to those areas identified as having a high risk of violence; and

(v) promptly reporting crimes committed against nurses to appropriate law enforcement agencies.

(7) Safe patient handling and movement practices.

(A) The hospital shall adopt, implement and enforce policies and procedures to identify, assess, and develop strategies to control risk of injury to patients and nurses associated with the lifting, transferring, repositioning, or movement of a patient.

(B) The policies and procedures shall establish a process that, at a minimum, includes the following:

(i) analysis of the risk of injury to both patients and nurses posed by the patient handling needs of the patient populations served by the hospital and the physical environment in which patient handling and movement occurs;

(ii) education of nurses in the identification, assessment, and control of risks of injury to patients and nurses during patient handling;

(iii) evaluation of alternative ways to reduce risks associated with patient handling, including evaluation of equipment and the environment;

(iv) restriction, to the extent feasible with existing equipment and aids, of manual patient handling or movement of all or most of a patient's weight to emergency, life-threatening, or otherwise exceptional circumstances;

(v) collaboration with and annual report to the nurse staffing committee;

(vi) procedures for nurses to refuse to perform or be involved in patient handling or movement that the nurse believes in good faith will expose a patient or a nurse to an unacceptable risk of injury;

(vii) submission of an annual report to the governing body on activities related to the identification, assessment, and development of strategies to control risk of injury to patients and nurses associated with the lifting, transferring, repositioning, or movement of a patient; and

(viii) development of architectural plans for constructing or remodeling a hospital or a unit of a hospital in which patient handling and movement occurs, with consideration of the feasibility of incorporating patient handling equipment or the physical space and construction design needed to incorporate that equipment at a later date.

(p) Outpatient services. If the hospital provides outpatient services, the services shall meet the needs of the patients in accordance with acceptable standards of practice.

(1) Organization. Outpatient services shall be appropriately organized and integrated with inpatient services.

(2) Personnel.

(A) The hospital shall assign an individual to be responsible for outpatient services.

(B) The hospital shall have appropriate physicians on staff and other professional and nonprofessional personnel available.

(q) Pharmacy services. The hospital shall provide pharmaceutical services that meet the needs of the patients.

(1) Compliance. The hospital shall provide a pharmacy which is licensed, as required, by the Texas State Board of Pharmacy. Pharmacy services shall comply with all applicable statutes and rules.

(2) Organization. The hospital shall have a pharmacy directed by a licensed pharmacist.

(3) Medical staff. The medical staff shall be responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical services.

(4) Pharmacy management and administration. The pharmacy or drug storage area shall be administered in accordance with accepted professional principles.

(A) Standards of practice as defined by state law shall be followed regarding the provision of pharmacy services.

(B) The pharmaceutical services shall have an adequate number of personnel to ensure quality pharmaceutical services including emergency services.

(i) The staff shall be sufficient in number and training to respond to the pharmaceutical needs of the patient population being served. There shall be an arrangement for emergency services.

(ii) Employees shall provide pharmaceutical services within the scope of their license and education.

(C) Drugs and biologicals shall be properly stored to ensure ventilation, light, security, and temperature controls.

(D) Records shall have sufficient detail to follow the flow of drugs from entry through dispensation.

(E) There shall be adequate controls over all drugs and medications including the floor stock. Drug storage areas shall be approved by the pharmacist, and floor stock lists shall be established.

(F) Inspections of drug storage areas shall be conducted throughout the hospital under pharmacist supervision.

(G) There shall be a drug recall procedure.

(H) A full-time, part-time, or consulting pharmacist shall be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(i) Direction of pharmaceutical services may not require on-premises supervision but may be accomplished through regularly scheduled visits in accordance with state law.

(ii) A job description or other written agreement shall clearly define the responsibilities of the pharmacist.

(I) Current and accurate records shall be kept of the receipt and disposition of all scheduled drugs.

(i) There shall be a record system in place that provides the information on controlled substances in a readily retrievable manner which is separate from the patient record.

(ii) Records shall trace the movement of scheduled drugs throughout the services, documenting utilization or wastage.

(iii) The pharmacist shall be responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled with written orders.

(5) Delivery of services. In order to provide patient safety, drugs and biologicals shall be controlled and distributed in accordance with applicable standards of practice, consistent with federal and state laws.

(A) All compounding, packaging, and dispensing of drugs and biologicals shall be under the supervision of a pharmacist and performed consistent with federal and state laws.

(B) All drugs and biologicals shall be kept in a secure area, and locked when appropriate.

(i) A policy shall be adopted, implemented, and enforced to ensure the safeguarding, transferring, and availability of keys to the locked storage area.

(ii) Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 shall be kept locked within a secure area.

(C) Outdated, mislabeled, or otherwise unusable drugs and biologicals shall not be available for patient use.

(D) When a pharmacist is not available, drugs and biologicals shall be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with federal and state laws.

(i) There shall be a current list of individuals identified by name and qualifications who are designated to remove drugs from the pharmacy.

(ii) Only amounts sufficient for immediate therapeutic needs shall be removed.

(E) Drugs and biologicals not specifically prescribed as to time or number of doses shall automatically be stopped after a reasonable time that is predetermined by the medical staff.

(i) Stop order policies and procedures shall be consistent with those of the nursing staff and the medical staff rules and regulations.

(ii) A protocol shall be established by the medical staff for the implementation of the stop order policy, in order that drugs shall be reviewed and renewed, or automatically stopped.

(iii) A system shall be in place to determine compliance with the stop order policy.

(F) Drug administration errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assessment and performance improvement program. There shall be a mechanism in place for capturing, reviewing, and tracking medication errors and adverse drug reactions.

(G) Abuses and losses of controlled substances shall be reported, in accordance with applicable federal and state laws, to the individual responsible for the pharmaceutical services, and to the chief executive officer, as appropriate.

(H) Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be immediately available to the professional staff.

(i) A pharmacist shall be readily accessible by telephone or other means to discuss drug therapy, interactions, side effects, dosage, assist in drug selection, and assist in the identification of drug induced problems.

(ii) There shall be staff development programs on drug therapy available to facility staff to cover such topics as new drugs added to the formulary, how to resolve drug therapy problems, and other general information as the need arises.

(I) A formulary system shall be established by the medical staff to ensure quality pharmaceuticals at reasonable costs.

(r) Quality assessment and performance improvement. The governing body shall ensure that there is an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement (QAPI) program to evaluate the provision of patient care.

(1) Program scope. The hospital-wide QAPI program shall reflect the complexity of the hospital's organization and services and have a written plan of implementation. The program must include an ongoing program that shows measurable improvements in the indicators for which there is evidence that they will improve health outcomes, and identify and reduce medical errors.

(A) All hospital departments and services, including services furnished under contract or arrangement shall be evaluated.

(B) Health care associated infections shall be evaluated.

(C) Medication therapy shall be evaluated.

(D) All medical and surgical services performed in the hospital shall be evaluated as they relate to appropriateness of diagnosis and treatment.

(E) The program must measure, analyze and track quality indicators, including adverse patients' events, and other aspects of performance that assess processes of care, hospital services and operations.

(F) Data collected must be used to monitor the effectiveness and safety of service and quality of care, and to identify opportunities for changes that will lead to improvement.

(G) Priorities must be established for performance improvement activities that focus on high-risk, high-volume, or problem-prone areas, taking into consideration the incidence, prevalence and severity of problems in those areas, and how health outcomes and quality of care may be affected.

(H) Performance improvement activities which affect patient safety, including analysis of medical errors and adverse patient events, must be established, and preventive actions implemented.

(I) Success of actions implemented as a result of performance improvement activities must be measured, and ongoing performance must be tracked to ensure improvements are sustained.

(2) Responsibility and accountability. The hospital's governing body, medical staff and administrative staff are responsible and accountable for ensuring that:

(A) an ongoing program for quality improvement is defined, implemented and maintained, and that program requirements are met;

(B) an ongoing program for patient safety, including reduction of medical errors, is defined, implemented and maintained;

(C) the hospital-wide QAPI efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated; and

(D) adequate resources are allocated for measuring, assessing, improving and sustaining the hospital's resources, and for reducing risk to patients.

(3) Medically-related patient care services. The hospital shall have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients. The hospital also shall have an effective, ongoing discharge planning program that facilitates the provision of follow-up care.

(A) Discharge planning shall be completed prior to discharge.

(B) Patients, along with necessary medical information, shall be transferred or referred to appropriate facilities, agencies, or outpatient services, as needed for follow-up or ancillary care.

(4) Implementation. The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

(s) Radiology services. The hospital shall maintain, or have available, diagnostic radiologic services according to needs of the patients. All radiology equipment, including X-ray equipment, mammography equipment and laser equipment, shall be licensed and registered as required under Chapter 289 of this title (relating to Radiation Control). If therapeutic services are also provided, the services, as well as the diagnostic services, shall meet professionally approved standards for safety and personnel qualifications as required in §§289.227, 289.229, 289.230 and 289.231 of this title (relating to Registration Regulations). In a special hospital, portable X-ray equipment may be acceptable as a minimum requirement.

(1) Policies and procedures. Policies and procedures shall be adopted, implemented and enforced which will describe the radiology services provided in the hospital and how employee and patient safety will be maintained.

(2) Safety for patients and personnel. The radiology services, particularly ionizing radiology procedures, shall minimize hazards to patients and personnel.

(A) Proper safety precautions shall be maintained against radiation hazards. This includes adequate radiation shielding, safety procedures and equipment maintenance and testing.

(B) Inspection of equipment shall be made by or under the supervision of a licensed medical physicist in accordance with §289.227(o) of this title (relating to Use of Radiation Machines in the Healing Arts). Defective equipment shall be promptly repaired or replaced.

(C) Radiation workers shall be provided personnel monitoring dosimeters to measure the amount of radiation exposure they receive. Exposure reports and documentation shall be available for review.

(D) Radiology services shall be provided only on the order of individuals granted privileges by the medical staff.

(3) Personnel.

(A) A qualified full-time, part-time, or consulting radiologist shall supervise the ionizing radiology services and shall interpret only those radiology tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section a radiologist is a physician who is qualified by education and experience in radiology in accordance with medical staff bylaws.

(B) Only personnel designated as qualified by the medical staff shall use the radiology equipment and administer procedures.

(4) Records. Records of radiology services shall be maintained. The radiologist or other individuals who have been granted privileges to perform radiology services shall sign reports of his or her interpretations.

(t) Renal dialysis services.

(1) Equipment.

(A) Maintenance and repair. All equipment used by a facility, including backup equipment, shall be operated within manufacturer's specifications, and maintained free of defects which could be a potential hazard to patients, staff, or visitors. Maintenance and repair of all equipment shall be performed by qualified staff or contract personnel.

(i) Staff shall be able to identify malfunctioning equipment and report such equipment to the appropriate staff for immediate repair.

(ii) Medical equipment that malfunctions must be clearly labeled and immediately removed from service until the malfunction is identified and corrected.

(iii) Written evidence of all maintenance and repairs shall be maintained.

(iv) After repairs or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning to service. This testing must be documented.

(v) A facility shall comply with the federal Food, Drug, and Cosmetic Act, 21 United States Code (USC), §360i(b), concerning reporting when a medical device as defined in 21 USC §321(h) has or may have caused or contributed to the injury or death of a patient of the facility.

(B) Preventive maintenance. A facility shall develop, implement and enforce a written preventive maintenance program to ensure patient care related equipment used in a facility receives electrical safety inspections, if appropriate, and maintenance at least annually or more frequently as recommended by the manufacturer. The preventive maintenance may be provided by facility staff or by contract.

(C) Backup machine. At least one complete dialysis machine shall be available on site as backup for every ten dialysis machines in use. At least one of these backup machines must be completely operational during hours of treatment. Machines not in use during a patient shift may be counted as backup except at the time of an initial or an expansion survey.

(D) Pediatric patients. If pediatric patients are treated, a facility shall use equipment and supplies, to include blood pressure cuffs, dialyzers, and blood tubing, appropriate for this special population.

(E) Emergency equipment and supplies. A facility shall have emergency equipment and supplies immediately accessible in the treatment area.

(i) At a minimum, the emergency equipment and supplies shall include the following:

(I) oxygen;

(II) mechanical ventilatory assistance equipment, to include airways, manual breathing bag, and mask;

(III) suction equipment;

(IV) supplies specified by the medical director;

(V) electrocardiograph; and

(VI) automated external defibrillator or defibrillator.

(ii) If pediatric patients are treated, the facility shall have the appropriate type and size emergency equipment and supplies listed in clause (i) of this subparagraph for this special population.

(iii) A facility shall establish, implement, and enforce a policy for the periodic testing and maintenance of the emergency equipment. Staff shall properly maintain and test the emergency equipment and supplies and document the testing and maintenance.

(F) Transducer protector. A transducer protector shall be replaced when wetted during a dialysis treatment and shall be used for one treatment only.

(2) Water treatment and dialysate concentrates.

(A) Compliance required. A facility shall meet the requirements of this section. A facility may follow more stringent requirements than the minimum standards required by this section.

(i) The facility administrator and medical director shall each demonstrate responsibility for the water treatment and dialysate supply systems to protect hemodialysis patients from adverse effects arising from known chemical and microbial contaminates that may be found in improperly prepared dialysate, to ensure that the dialysate is correctly formulated and meets the requirements of all applicable quality standards.

(ii) The facility administrator and medical director must assure that policies and procedures related to water treatment and dialysate are understandable and accessible to the operator(s) and that the training program includes quality testing, risks and hazards of improperly prepared concentrate and bacterial issues.

(iii) The facility administrator and medical director must be informed prior to any alteration of, or any device being added to, the water system.

(B) Water treatment. These requirements apply to water intended for use in the delivery of hemodialysis, including the preparation of concentrates from powder at a dialysis facility and dialysate.

(i) The design for the water treatment system in a facility shall be based on considerations of the source water for the facility and designed by a water quality professional with education, training, or experience in dialysis system design.

(ii) When a public water system supply is not used by a facility, the source water shall be tested by the facility at monthly intervals in the same manner as a public water system as described in 30 TAC §290.104 (relating to Summary of Maximum Contaminant Levels, Maximum Residual Disinfectant Levels, Treatment Techniques, and Action Levels) and §290.109 (relating to Microbial Contaminants) as adopted by the Texas Commission on Environmental Quality (TCEQ).

(iii) The physical space in which the water treatment system is located must be adequate to allow for maintenance, testing, and repair of equipment. If mixing of dialysate is performed in the same area, the physical space must also be adequate to house and allow for the maintenance, testing, and repair of the mixing equipment and for performing the mixing procedure.

(iv) The water treatment system components shall be arranged and maintained so that bacterial and chemical contaminant levels in the product water do not exceed the standards for hemodialysis water quality described in §4.2.1 (concerning Water Bacteriology) and §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the Association for the Advancement of Medical Instrumentation (AAMI). All documents published by the AAMI as referenced in this section may be obtained by writing the following address: 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201.

(v) Written policies and procedures for the operation of the water treatment system must be developed and implemented. Parameters for the operation of each component of the water treatment system must be developed in writing and known to the operator. Each major water system component shall be labeled in a manner that identifies the device; describes its function, how performance is verified and actions to take in the event performance is not within an acceptable range.

(vi) The materials of any components of water treatment systems (including piping, storage, filters and distribution systems) that contact the purified water shall not interact chemically or physically so as to affect the purity or quality of the product water adversely. Such components shall be fabricated from unreactive materials (e.g. plastics) or appropriate stainless steel. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, or aluminum, is prohibited.

(vii) Chemicals infused into the water such as iodine, acid, flocculants, and complexing agents shall be shown to be nondialyzable or shall be adequately removed from product water. Monitors or specific test procedures to verify removal of additives shall be provided and documented.

(viii) Each water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of two carbon tanks in series. If the source water is from a private supply which does not use chlorine/chloramine, the water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of one carbon tank.

(I) Reverse osmosis membranes. Reverse osmosis membranes, if used, shall meet the standards in §4.3.7 (concerning Reverse Osmosis) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the AAMI.

(II) Deionization systems.

(-a-) Deionization systems, if used, shall be monitored continuously to produce water of one megohm-centimeter (cm) or greater specific resistivity (or conductivity of one microsiemen/cm or less) at 25 degrees Celsius. An audible and visual alarm shall be activated when the product water resistivity falls below this level and the product water stream shall be prevented from reaching any point of use.

(-b-) Patients shall not be dialyzed on deionized water with a resistivity less than 1.0 megohm-cm measured at the output of the deionizer.

(-c-) A minimum of two deionization (DI) tanks in series shall be used with resistivity monitors including audible and visual alarms placed pre and post the final DI tank in the system. The alarms must be audible in the patient care area.

(-d-) Feed water for deionization systems shall be pretreated with activated carbon adsorption, or a comparable alternative, to prevent nitrosamine formation.

(-e-) If a deionization system is the last process in a water treatment system, it shall be followed by an ultrafilter or other bacteria and endotoxin reducing device.

(III) Carbon tanks.

(-a-) The carbon tanks must contain acid washed carbon, 30-mesh or smaller with a minimum iodine number of 900.

(-b-) A minimum of two carbon adsorption beds shall be installed in a series configuration.

(-c-) The total empty bed contact time (EBCT) shall be at least ten minutes, with the final tank providing at least five minutes EBCT. Carbon adsorption systems used to prepare water for portable dialysis systems are exempt from the requirement for the second carbon and a ten minute EBCT if removal of chloramines to below 0.1 milligram (mg)/1 is verified before each treatment.

(-d-) A means shall be provided to sample the product water immediately prior to the final bed(s). Water from this port(s) must be tested for chlorine/chloramine levels immediately prior to each patient shift.

(-e-) All samples for chlorine/chloramine testing must be drawn when the water treatment system has been operating for at least 15 minutes.

(-f-) Tests for total chlorine, which include both free and combined forms of chlorine, may be used as a single analysis with the maximum allowable concentration of 0.1 mg/liter (L). Test results of greater than 0.5 parts per million (ppm) for chlorine or 0.1 ppm for chloramine from the port between the initial tank(s) and final tank(s) shall require testing to be performed at the final exit and replacement of the initial tank(s).

(-g-) In a system without a holding tank, if test results at the exit of the final tank(s) are greater than the parameters for chlorine or chloramine described in this subclause, dialysis treatment shall be immediately terminated to protect patients from exposure to chlorine/chloramine and the medical director shall be notified. In systems with holding tanks, if the holding tank tests <0.1 mg/L for total chlorine, the reverse osmosis (RO) may be turned off and the product water in the holding tank may be used to finish treatments in process. The medical director shall be notified.

(-h-) If means other than granulated carbon are used to remove chlorine/chloramine, the facility's governing body must approve such use in writing after review of the safety of the intended method for use in hemodialysis applications. If such methods include the use of additives, there must be evidence the product water does not contain unsafe levels of these additives.

(ix) Water softeners, if used, shall be tested at the end of the treatment day to verify their capacity to treat a sufficient volume of water to supply the facility for the entire treatment day and shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration.

(x) If used, the face(s) of timer(s) used to control any component of the water treatment or dialysate delivery system shall be visible to the operator at all times. Written evidence that timers are checked for operation and accuracy each day of operation must be maintained.

(xi) Filter housings, if used during disinfectant procedures, shall include a means to clear the lower portion of the housing of the disinfecting agents. Filter housings shall be opaque.

(xii) Ultrafilters, or other bacterial reducing filters, if used, shall be fitted with pressure gauges on the inlet and outlet water lines to monitor the pressure drop across the membrane. Ultrafilters shall be included in routine disinfection procedures.

(xiii) If used, storage tanks shall have a conical or bowl shaped base and shall drain from the lowest point of the base. Storage tanks shall have a tight-fitting lid and be vented through a hydrophobic 0.2 micron air filter. Means shall be provided to effectively disinfect any storage tank installed in a water distribution system.

(xiv) Ultraviolet (UV) lights, if used, shall be monitored at the frequency recommended by the manufacturer. A log sheet shall be used to record monitoring.

(xv) Water treatment system piping shall be labeled to indicate the contents of the pipe and direction of flow.

(xvi) The water treatment system must be continuously monitored during patient treatment and be guarded by audible and visual alarms which can be seen and heard in the dialysis treatment area should water quality drop below specific parameters. Quality monitor sensing cells shall be located as the last component of the water treatment system and at the beginning of the distribution system. No water treatment components that could affect the quality of the product water as measured by this device shall be located after the sensing cell.

(xvii) When deionization tanks do not follow a reverse osmosis system, parameters for the rejection rate of the membranes must assure that the lowest rate accepted would provide product water in compliance with §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition published by the AAMI.

(xviii) A facility shall maintain written logs of the operation of the water treatment system for each treatment day. The log book shall include each component's operating parameter and the action taken when a component is not within the facility's set parameters.

(xix) Microbiological testing of product water shall be conducted.

(I) Frequency. Microbiological testing shall be conducted monthly and following any repair or change to the water treatment system. For a newly installed water distribution system, or when a change has been made to an existing system, weekly testing shall be conducted for one month to verify that bacteria and endotoxin levels are consistently within the allowed limits.

(II) Sample sites. At a minimum, sample sites chosen for the testing shall include the beginning of the distribution piping, at any site of dialysate mixing, and the end of the distribution piping.

(III) Technique. Samples shall be collected immediately before sanitization/disinfection of the water treatment system and dialysis machines. Water testing results shall be routinely trended and reviewed by the medical director in order to determine if results seem questionable or if there is an opportunity for improvement.

The medical director shall determine if there is a need for retesting. Repeated results of "no growth" shall be validated via an outside laboratory. A calibrated loop may not be used in microbiological testing of water samples. Colonies shall be counted using a magnifying device.

(IV) Expected results. Product water used to prepare dialysate, concentrates from powder, or to reprocess dialyzers for multiple use, shall contain a total viable microbial count less than 200 colony forming units (CFU)/millimeter (ml) and an endotoxin concentration less than 2 endotoxin units (EU)/ml. The action level for the total viable microbial count in the product water shall be 50 CFU/ml and the action level for the endotoxin concentration shall be 1 EU/ml.

(V) Required action for unacceptable results. If the action levels described at subclause (IV) of this clause are observed in the product water, corrective measures shall be taken promptly to reduce the levels into an acceptable range.

(VI) Records. All bacteria and endotoxin results shall be recorded on a log sheet in order to identify trends that may indicate the need for corrective action.

(xx) If ozone generators are used to disinfect any portion of the water or dialysate delivery system, testing based on the manufacturer's direction shall be used to measure the ozone concentration each time disinfection is performed, to include testing for safe levels of residual ozone at the end of the disinfection cycle. Testing for ozone in the ambient air shall be conducted on a periodic basis as recommended by the manufacturer. Records of all testing must be maintained in a log.

(xxi) If used, hot water disinfection systems shall be monitored for temperature and time of exposure to hot water as specified by the manufacturer. Temperature of the water shall be recorded at a point furthest from the water heater, where the lowest water temperature is likely to occur. The water temperature shall be measured each time a disinfection cycle is performed. A record that verifies successful completion of the heat disinfection shall be maintained.

(xxii) After chemical disinfection, means shall be provided to restore the equipment and the system in which it is installed to a safe condition relative to residual disinfectant prior to the product water being used for dialysis applications.

(xxiii) Samples of product water must be submitted for chemical analysis every six months and must demonstrate that the quality of the product water used to prepare dialysate or concentrates from powder, meets §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the AAMI.

(I) Samples for chemical analysis shall be collected at the end of the water treatment components and at the most distal point in each water distribution loop, if applicable. All other outlets from the distribution loops shall be inspected to ensure that the outlets are fabricated from compatible materials. Appropriate containers and pH adjustments shall be used to ensure accurate determinations. New facilities or facilities that add or change the configuration of the water distribution system must draw samples at the most distal point for each water distribution loop, if applicable, on a one time basis.

(II) Additional chemical analysis shall be submitted if substantial changes are made to the water treatment system or if the percent rejection of a reverse osmosis system decreased 5.0% or more from the percent rejection measured at the time the water sample for the preceding chemical analysis was taken.

(xxiv) Facility records must include all test results and evidence that the medical director has reviewed the results of the water quality testing and directed corrective action when indicated.

(xxv) Only persons qualified by the education or experience may operate, repair, or replace components of the water treatment system.

(C) Dialysate.

(i) Quality control procedures shall be established to ensure ongoing conformance to policies and procedures regarding dialysate quality.

(ii) Each facility shall set all hemodialysis machines to use only one family of concentrates. When new machines are put into service or the concentrate family or concentrate manufacturer is changed, samples shall be sent to a laboratory for verification.

(iii) Prior to each patient treatment, staff shall verify the dialysate conductivity and pH of each machine with an independent device.

(iv) Bacteriological testing shall be conducted.

(I) Frequency. Responsible facility staff shall develop a schedule to ensure each hemodialysis machine is tested quarterly for bacterial growth and the presence of endotoxins. Hemodialysis machines of home patients shall be cultured monthly until results not exceeding 200 CFU/ml are obtained for three consecutive months, then quarterly samples shall be cultured.

(II) Acceptable limits. Dialysate shall contain less than 200 CFU/ml and an endotoxin concentration of less than 2 EU/ml. The action level for total viable microbial count shall be 50 CFU/ml and the action level for endotoxin concentration shall be 1 EU/ml.

(III) Action to be taken. Disinfection and retesting shall be done when bacterial or endotoxin counts exceed the action levels. Additional samples shall be collected when there is a clinical indication of a pyrogenic reaction and/or septicemia.

(v) Only a licensed nurse may use an additive to increase concentrations of specific electrolytes in the acid concentrate. Mixing procedures shall be followed as specified by the additive manufacturer. When additives are prescribed for a specific patient, the container holding the prescribed acid concentrate shall be labeled with the name of the patient, the final concentration of the added electrolyte, the date the prescribed concentrate was made, and the name of the person who mixed the additive.

(vi) All components used in concentrate preparation systems (including mixing and storage tanks, pumps, valves and piping) shall be fabricated from materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the concentrate so as to affect its purity, or with the germicides used to disinfect the equipment. The use of materials that are known to cause toxicity in hemodialysis such as copper, brass, galvanized material and aluminum is prohibited.

(vii) Facility policies shall address means to protect stored acid concentrates from tampering or from degeneration due to exposure to extreme heat or cold.

(viii) Procedures to control the transfer of acid concentrates from the delivery container to the storage tank and prevent the inadvertent mixing of different concentrate formulations shall be developed, implemented and enforced. The storage tanks shall be clearly labeled.

(ix) Concentrate mixing systems shall include a purified water source, a suitable drain, and a ground fault protected electrical outlet.

(I) Operators of mixing systems shall use personal protective equipment as specified by the manufacturer during all mixing processes.

(II) The manufacturer's instructions for use of a concentrate mixing system shall be followed, including instructions for mixing the powder with the correct amount of water. The number of bags or weight of powder added shall be determined and recorded.

(III) The mixing tank shall be clearly labeled to indicate the fill and final volumes required to correctly dilute the powder.

(IV) Systems for preparing either bicarbonate or acid concentrate from powder shall be monitored according to the manufacturer's instructions.

(V) Concentrates shall not be used, or transferred to holding tanks or distribution systems, until all tests are completed.

(VI) If a facility designs its own system for mixing concentrates, procedures shall be developed and validated using an independent laboratory to ensure proper mixing.

(x) Acid concentrate mixing tanks shall be designed to allow the inside of the tank to be rinsed when changing concentrate formulas.

(I) Acid mixing systems shall be designed and maintained to prevent rust and corrosion.

(II) Acid concentrate mixing tanks shall be emptied completely and rinsed with product water before mixing another batch of concentrate to prevent cross contamination between different batches.

(III) Acid concentrate mixing equipment shall be disinfected as specified by the equipment manufacturer or in the case where no specifications are given, as defined by facility policy.

(IV) Records of disinfection and rinsing of disinfectants to safe residual levels shall be maintained.

(xi) Bicarbonate concentrate mixing tanks shall have conical or bowl shaped bottoms and shall drain from the lowest point of the base. The tank design shall allow all internal surfaces to be disinfected and rinsed.

(I) Bicarbonate concentrate mixing tanks shall not be prefilled the night before use.

(II) If disinfectant remains in the mixing tank overnight, this solution must be completely drained, the tank rinsed and tested for residual disinfectant prior to preparing the first batch of that day of bicarbonate concentrate.

(III) Unused portions of bicarbonate concentrate shall not be mixed with fresh concentrate.

(IV) At a minimum, bicarbonate distribution systems shall be disinfected weekly. More frequent disinfection shall be done if required by the manufacturer, or if dialysate culture results are above the action level.

(V) If jugs are reused to deliver bicarbonate concentrate to individual hemodialysis machines:

(-a-) jugs shall be emptied of concentrate, rinsed and inverted to drain at the end of each treatment day;

(-b-) at a minimum, jugs shall be disinfected weekly, more frequent disinfection shall be considered by the medical director if dialysate culture results are above the action level; and

(-c-) following disinfection, jugs shall be drained, rinsed free of residual disinfectant, and inverted to dry. Testing for residual disinfectant shall be done and documented.

(xii) All mixing tanks, bulk storage tanks, dispensing tanks and containers for single hemodialysis treatments shall be labeled as to the contents.

(I) Mixing tanks. Prior to batch preparation, a label shall be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling shall remain on the mixing tank until the tank has been emptied.

(II) Bulk storage/dispensing tanks. These tanks shall be permanently labeled to identify the chemical composition or formulation of their contents.

(III) Single machine containers. At a minimum, single machine containers shall be labeled with sufficient information to differentiate the contents from other concentrate formulations used in the facility and permit positive identification by users of container contents.

(xiii) Permanent records of batches produced shall be maintained to include the concentrate formula produced, the volume of the batch, lot number(s) of powdered concentrate packages, the manufacturer of the powdered concentrate, date and time of mixing, test results, person performing mixing, and expiration date (if applicable).

(xiv) If dialysate concentrates are prepared in the facility, the manufacturers' recommendations shall be followed regarding any preventive maintenance. Records shall be maintained indicating the date, time, person performing the procedure, and the results (if applicable).

(3) Prevention requirements concerning patients.

(A) Hepatitis B vaccination.

(i) With the advice and consent of a patient's attending nephrologist, facility staff shall make the hepatitis B vaccine available to a patient who is susceptible to hepatitis B, provided that the patient has coverage or is willing to pay for vaccination.

(ii) The facility shall make available to patients literature describing the risks and benefits of the hepatitis B vaccination.

(B) Serologic screening of patients.

(i) A patient new to dialysis shall have been screened for hepatitis B surface antigen (HBsAg) within one month before or at the time of admission to the facility or have a known hepatitis B surface antibody (anti-HBs) status of at least 10 milli-international units per milliliter no more than 12 months prior to admission. The facility shall document how this screening requirement is met.

(ii) Repeated serologic screening shall be based on the antigen or antibody status of the patient.

(I) Monthly screening for HBsAg is required for patients whose previous test results are negative for HBsAg.

(II) Screening of HBsAg-positive or anti-HBs-positive patients may be performed on a less frequent basis, provided that the facility's policy on this subject remains congruent with Appendices i and ii of the National Surveillance of Dialysis Associated

Disease in the United States, 2000, published by the United States Department of Health and Human Services.

(C) Isolation procedures for the HBsAg-positive patient.

(i) The facility shall treat patients positive for HBsAg in a segregated treatment area which includes a hand washing sink, a work area, patient care supplies and equipment, and sufficient space to prevent cross-contamination to other patients.

(ii) A patient who tests positive for HBsAg shall be dialyzed on equipment reserved and maintained for the HBsAg-positive patient's use only.

(iii) When a caregiver is assigned to both HBsAg-negative and HBsAg-positive patients, the HBsAg-negative patients assigned to this grouping must be Hepatitis B antibody positive. Hepatitis B antibody positive patients are to be seated at the treatment stations nearest the isolation station and be assigned to the same staff member who is caring for the HBsAg-positive patient.

(iv) If an HBsAg-positive patient is discharged, the equipment which had been reserved for that patient shall be given intermediate level disinfection prior to use for a patient testing negative for HBsAg.

(v) In the case of patients new to dialysis, if these patients are admitted for treatment before results of HBsAg or anti-HBs testing are known, these patients shall undergo treatment as if the HBsAg test results were potentially positive, except that they shall not be treated in the HBsAg isolation room, area, or machine.

(I) The facility shall treat potentially HBsAg-positive patients in a location in the treatment area which is outside of traffic patterns until the HBsAg test results are known.

(II) The dialysis machine used by this patient shall be given intermediate level disinfection prior to its use by another patient.

(III) The facility shall obtain HBsAg status results of the patient no later than three days from admission.

(u) Respiratory care services. The hospital shall meet the needs of the patients in accordance with acceptable standards of practice.

(1) Policies and procedures shall be adopted, implemented, and enforced which describe the provision of respiratory care services in the hospital.

(2) The organization of the respiratory care services shall be appropriate to the scope and complexity of the services offered.

(3) There shall be a medical director or clinical director of respiratory care services who is a physician with the knowledge, experience, and capabilities to supervise and administer the services properly. The medical director or clinical director may serve on either a full-time or part-time basis.

(4) There shall be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with the state law.

(5) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures shall be designated in writing.

(6) If blood gases or other clinical laboratory tests are performed by the respiratory care services staff, the respiratory care staff shall comply with CLIA 1988 in accordance with the requirements specified in 42 CFR, Part 493.

(7) Services shall be provided only on, and in accordance with, the orders of a physician.

(v) Sterilization and sterile supplies.

(1) Supervision. The sterilization of all supplies and equipment shall be under the supervision of a person qualified by education, training and experience. Staff responsible for the sterilization of supplies and equipment shall participate in a documented continuing education program; new employees shall receive initial orientation and on-the-job training.

(2) Equipment and procedures.

(A) Sterilization. Every hospital shall provide equipment adequate for sterilization of supplies and equipment as needed. Equipment shall be maintained and operated to perform, with accuracy, the sterilization of the various materials required.

(B) Written policy. Written policies and procedures for the decontamination and sterilization activities performed shall be adopted, implemented and enforced. Policies shall include the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of reusable items, as well as those for the assembly, wrapping, storage, distribution and quality control of sterile items and equipment. These written policies shall be reviewed at least every other year and approved by the infection control practitioner or committee.

(C) Separation. Where cleaning, preparation, and sterilization functions are performed in the same room or unit, the physical facilities, equipment, and the policies and procedures for their use, shall be such as to effectively separate soiled or contaminated supplies and equipment from the clean or sterilized supplies and equipment. Hand washing facilities shall be provided and a separate sink shall be provided for safe disposal of liquid waste.

(D) Labeling. All containers for solutions, drugs, flammable solvents, ether, alcohol, and medicated supplies shall be clearly labeled to indicate contents. Those which are sterilized by the hospital shall be labeled so as to be identifiable both before and after sterilization. Sterilized items shall have a load control identification that indicates the sterilizer used, the cycle or load number, and the date of sterilization.

(E) Preparation for sterilization.

(i) All items to be sterilized shall be prepared to reduce the bioburden. All items shall be thoroughly cleaned, decontaminated and prepared in a clean, controlled environment.

(ii) All articles to be sterilized shall be arranged so all surfaces will be directly exposed to the sterilizing agent for the prescribed time and temperature.

(F) Packaging. All wrapped articles to be sterilized shall be packaged in materials recommended for the specific type of sterilizer and material to be sterilized.

(G) External chemical indicators.

(i) External chemical indicators, also known as sterilization process indicators, shall be used on each package to be sterilized, including items being flash sterilized to indicate that items have been exposed to the sterilization process.

(ii) The indicator results shall be interpreted according to manufacturer's written instructions and indicator reaction specifications.

(iii) A log shall be maintained with the load identification, indicator results, and identification of the contents of the load.

(H) Biological indicators. Biological indicators are commercially-available microorganisms (e.g., United States Food and Drug Administration (FDA) approved strips or vials of Bacillus species endospores) which can be used to verify the performance of waste treatment equipment and processes (or sterilization equipment and processes).

(i) The efficacy of the sterilizing process shall be monitored with reliable biological indicators appropriate for the type of sterilizer used.

(ii) Biological indicators shall be included in at least one run each week of use for steam sterilizers, at least one run each day of use for low-temperature hydrogen peroxide gas sterilizers, and every load for ethylene oxide (EO) sterilizers.

(iii) Biological indicators shall be included in every load that contains implantable objects.

(iv) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load.

(v) If a test is positive, the sterilizer shall immediately be taken out of service.

(I) Implantable items shall be recalled and reprocessed if a biological indicator test (spore test) is positive.

(II) All available items shall be recalled and reprocessed if a sterilizer malfunction is found and a list of those items not retrieved in the recall shall be submitted to infection control.

(III) A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations.

(I) Sterilizers.

(i) Steam sterilizers (saturated steam under pressure) shall be utilized for sterilization of heat and moisture stable items. Steam sterilizers shall be used according to manufacturer's written instructions.

(ii) EO sterilizers shall be used for processing heat and moisture sensitive items. EO sterilizers and aerators shall be used and vented according to the manufacturer's written instructions.

(iii) Flash sterilizers shall be used for emergency sterilization of clean, unwrapped instruments and porous items only.

(J) Disinfection.

(i) Written policies, approved by the infection control committee, shall be adopted, implemented and enforced for the use of chemical disinfectants.

(ii) The manufacturer's written instructions for the use of disinfectants shall be followed.

(iii) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use.

(iv) Disinfectant solutions shall be kept covered and used in well-ventilated areas.

(v) Chemical germicides that are registered with the United States Environmental Protection Agency as "sterilants" may be used either for sterilization or high-level disinfection.

(vi) All staff personnel using chemical disinfectants shall have received training on their use.

(K) Performance records.

(i) Performance records for all sterilizers shall be maintained for each cycle. These records shall be retained and available for review for a minimum of five years.

(ii) Each sterilizer shall be monitored continuously during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained and shall include:

(I) the sterilizer identification;

(II) sterilization date;

(III) cycle number;

(IV) contents of each load;

(V) duration and temperature of exposure phase (if not provided on sterilizer recording charts);

(VI) identification of operator(s);

(VII) results of biological tests and dates performed;

(VIII) time-temperature recording charts from each sterilizer;

(IX) gas concentration and relative humidity (if applicable); and

(X) any other test results.

(L) Storage of sterilized items.

(i) Sterilized items shall be transported so as to maintain cleanliness and sterility and to prevent physical damage.

(ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.

(iii) The hospital shall adopt, implement and enforce a policy which describes the mechanism used to determine the shelf life of sterilized packages.

(M) Preventive maintenance. Preventive maintenance of all sterilizers shall be performed according to individual adopted, implemented and enforced policy on a scheduled basis by qualified personnel, using the sterilizer manufacturer's service manual as a reference. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least two years and shall be available for review.

(w) Surgical services. If a hospital provides surgical services, the services shall be well-organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services shall be consistent in quality with inpatient care in accordance with the complexity of services offered. A special hospital may not offer surgical services.

(1) Organization and staffing. The organization of the surgical services shall be appropriate for the scope of the services offered.

(A) The operating rooms shall be supervised by an experienced RN or physician.

(B) Licensed vocational nurses (LVNs) and surgical technologists (operating room technicians) may serve as scrub nurses or technologists under the supervision of an RN.

(C) Circulating duties in the operating room must be performed by qualified RNs. In accordance with approved medical

staff polices and procedures, LVNs and surgical technologists may assist in circulatory duties under the direct supervision of a qualified RN circulator.

(D) Surgical privileges shall be delineated for all physicians, podiatrists, and dentists performing surgery in accordance with the competencies of each. The surgical services shall maintain a roster specifying the surgical privileges of each.

(2) Delivery of service. Surgical services shall be consistent with needs and resources. Written policies governing surgical care which are designed to ensure the achievement and maintenance of high standards of medical practice and patient care shall be adopted, implemented and enforced.

(A) There shall be a complete medical history and physical examination, as required under subsection (k)(3)(F) of this section, in the medical record of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's medical record, there shall be a statement to that effect and an admission note in the record by the individual who admitted the patient.

(B) A properly executed informed consent form for the operation shall be in the patient's medical record before surgery, except in emergencies.

(C) The following equipment shall be available in the operating room suites:

(i) communication system;

(ii) cardiac monitor;

(iii) resuscitator;

(iv) defibrillator;

(v) aspirator; and

(vi) tracheotomy set.

(D) There shall be adequate provisions for immediate postoperative care.

(E) The operating room register shall be complete and up-to-date. The register shall contain, but not be limited to, the following:

(i) patient's name and hospital identification number;

(ii) date of operation;

(iii) operation performed;

(iv) operating surgeon and assistant(s);

(v) type of anesthesia used and name of person administering it;

(vi) time operation began and ended;

(vii) time anesthesia began and ended;

(viii) disposition of specimens;

(ix) names of scrub and circulating personnel;

(x) unusual occurrences; and

(xi) disposition of the patient.

(F) An operative report describing techniques, findings, and tissue removed or altered shall be written or dictated immediately following surgery and signed by the surgeon.

(x) Therapy services. If the hospital provides physical therapy, occupational therapy, audiology, or speech pathology services, the services shall be organized and staffed to ensure the health and safety of patients.

(1) Organization and staffing. The organization of the services shall be appropriate to the scope of the services offered.

(A) The director of the services shall have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(B) Physical therapy, occupational therapy, speech therapy, or audiology services, if provided, shall be provided by staff who meet the qualifications specified by the medical staff, consistent with state law.

(2) Delivery of services. Services shall be furnished in accordance with a written plan of treatment. Services to be provided shall be consistent with applicable state laws and regulations, and in accordance with orders of the physician, podiatrist, dentist or other licensed practitioner who is authorized by the medical staff to order the services. Therapy orders shall be incorporated in the patient's medical record.

(y) Waste and waste disposal.

(1) Special waste and liquid/sewage waste management.

(A) The hospital shall comply with the requirements set forth by the department in §§1.131 - 1.137 of this title (relating to Definition, Treatment, and Disposition of Special Waste from Health Care-Related Facilities) and the TCEQ requirements in 30 TAC §330.1207 (relating to Generators of Medical Waste).

(B) All sewage and liquid wastes shall be disposed of in a municipal sewerage system or a septic tank system permitted by the TCEQ in accordance with 30 TAC Chapter 285 (relating to On-Site Sewage Facilities).

(2) Waste receptacles.

(A) Waste receptacles shall be conveniently available in all toilet rooms, patient areas, staff work areas, and waiting rooms. Receptacles shall be routinely emptied of their contents at a central location(s) into closed containers.

(B) Waste receptacles shall be properly cleaned with soap and hot water, followed by treatment of inside surfaces of the receptacles with a germicidal agent.

(C) All containers for other municipal solid waste shall be leak-resistant, have tight-fitting covers, and be rodent-proof.

(D) Nonreusable containers shall be of suitable strength to minimize animal scavenging or rupture during collection operations.

§133.42. Patient Rights.

(a) Patient rights requirements for all hospitals.

(1) A hospital shall adopt, implement, and enforce a policy to ensure patients' rights. The written policy shall include:

(A) the right of the patient to the hospital's reasonable response to his or her requests and needs for treatment or service, within the hospital's capacity, its stated mission, and applicable law and regulation;

(B) the right of the patient to considerate and respectful care:

(i) the care of the patient includes consideration of the psychosocial, spiritual, and cultural variables that influence the perceptions of illness;

(ii) the care of the dying patient optimizes the comfort and dignity of the patient through:

(I) treating primary and secondary symptoms that respond to treatment as desired by the patient or surrogate decision maker;

(II) effectively managing pain; and

(III) acknowledging the psychosocial and spiritual concerns of the patient and the family regarding dying and the expression of grief by the patient and family;

(C) the right of the patient, in collaboration with his or her physician, to make decisions involving his or her health care, to include the following:

(i) the right of the patient to accept medical care or to refuse treatment to the extent permitted by law and to be informed of the medical consequences of such refusal; and

(ii) the right of the patient to formulate advance directives and to appoint a surrogate to make health care decisions on his or her behalf to the extent permitted by law. Advance directives are written instructions recognized under state law relating to the provision of health care when individuals are unable to communicate their wishes regarding medical treatment. The advance directive may be a written document authorizing an agent or surrogate to make decisions on an individual's behalf (a medical power of attorney for health care), a written or verbal statement (a living will), or some other form of instruction recognized under state law specifically addressing the provisions of health care;

(I) a hospital shall have in place a mechanism to ascertain the existence of, and, as appropriate, assist in the development of advance directives at the time of the patient's admission;

(II) the provision of care shall not be conditioned on the existence of an advance directive; and

(III) an advance directive(s) shall be in the patient's medical record and shall be reviewed periodically with the patient or surrogate decision maker if the patient has executed an advance directive;

(D) the right of the patient to the information necessary to enable him or her to make treatment decisions that reflect his or her wishes; a policy on informed decision making shall be adopted, implemented and enforced by the medical staff and governing body and shall be consistent with any legal requirements;

(E) the right of the patient to receive, at the time of admission, information about the hospital's patient rights policy(ies) and the mechanism for the initiation, review, and when possible, resolution of patient complaints concerning the quality of care;

(F) the right of the patient or the patient's designated representative to participate in the consideration of ethical issues that arise in the care of the patient. The hospital shall have a mechanism for the consideration of ethical issues arising in the care of patients and to provide education to care givers and patients on ethical issues in health care;

(G) the right of the patient to be informed of any human experimentation or other research or educational projects affecting his or her care or treatment;

(H) the right of the patient, within the limits of law, to personal privacy and confidentiality of information;

(I) the right of the patient or the patient's legally designated representative access to the information contained in the patient's medical record, within the limits of the law; and

(J) the right of the patient's guardian, next of kin, or legally authorized responsible person to exercise, to the extent permitted by law, the rights delineated on behalf of the patient if the patient:

(i) has been adjudicated incompetent in accordance with the law;

(ii) is found by his or her physician to be medically incapable of understanding the proposed treatment or procedure;

(iii) is unable to communicate his or her wishes regarding treatment; or

(iv) is a minor.

(2) The hospital patient's bill of rights shall be prominently and conspicuously posted for display in a public area of the facility that is readily available to patients, residents, employees, and visitors.

(b) Additional patient bill of rights requirements for hospitals providing comprehensive medical rehabilitation services. A hospital that provides comprehensive medical rehabilitation services shall comply with subsection (a) of this section and with the following additional provisions applicable to patients who receive such services.

(1) The patient's bill of rights shall address the rights of minors and provide that a minor is entitled to:

(A) appropriate treatment in the least restrictive setting available;

(B) not receive unnecessary or excessive medication;

(C) an individualized treatment plan and to participate in the development of the plan;

(D) a humane treatment environment that provides reasonable protection from harm and appropriate privacy for personal needs;

(E) separation from adult patients; and

(F) regular communication between the minor patient and the patient's family.

(2) Prior to admission or acceptance for evaluation, a written copy of the patient's bill of rights in the patient's primary language, if possible, shall be given to each patient, and, as appropriate, to the patient's parent, managing conservator, or guardian.

(3) The hospital shall ensure that within 24 hours after the patient is admitted to the hospital, the rights described in this subsection are explained to the patient and, if appropriate, to the patient's parent, managing conservator, or guardian in the following manner:

(A) orally, in simple, nontechnical terms in the person's primary language, if possible; or

(B) other reasonable means calculated to communicate with a person who has an impairment of vision or hearing, if applicable.

(4) If the patient cannot comprehend the information because of illness, age, or other factors, or an emergency exists that precludes immediate presentation of the information, or the patient refused to sign the written copy of the patient's bill of rights as provided for in paragraph (5) of this subsection, the presentation of the document shall be witnessed by two members of the hospital staff, and the unsigned patient's bill of rights shall be placed in the clinical record along with a note signed by the witnesses indicating the reasons for their signatures.

(5) The hospital shall obtain a signed copy of the patient's bill of rights from each patient, or, if appropriate, from the patient's parent, managing conservator, or guardian. The signed copy shall include a statement that the patient, patient's parent, managing conservator, or guardian has read the document and understands the rights specified in the document. The signed copy shall be made a part of the patient's medical record.

(c) Additional patient bill of rights requirements for hospitals providing chemical dependency services. A hospital that provides chemical dependency services shall comply with subsection (a) of this section and with §448.701 of this title (relating to Client Bill of Rights) applicable to patients who receive such services.

(d) Additional patient bill of rights requirements for hospitals providing mental health services. A hospital that provides mental health services shall comply with subsection (a) of this section and Chapter 404, Subchapter E of this title (relating to Rights of Persons Receiving Mental Health Services) applicable to patients who receive such services.

(e) Posting requirements for patient bill of rights for hospitals providing comprehensive medical rehabilitation services, chemical dependency services, or mental health services. The hospital shall prominently and conspicuously post for display a copy of the patient's bill of rights in a public area of the hospital that is readily visible to patients, residents, employees, and visitors. The patient bill of rights posted for display shall be in English and in a second language appropriate to the demographic makeup of the community served.

§133.45. Miscellaneous Policies and Protocols.

(a) Determination of death and autopsy reports. The hospital shall adopt, implement, and enforce protocols to be used in determining death and for filing autopsy reports which comply with Health and Safety Code (HSC), Title 8, Subtitle A, Chapter 671 (Determination of Death and Autopsy Reports).

(b) Organ and tissue donors. The hospital shall adopt, implement, and enforce a written protocol to identify potential organ and tissue donors which is in compliance with the Texas Anatomical Gift Act, HSC, Chapter 692. The hospital shall make its protocol available to the public during the hospital's normal business hours.

(1) The hospital's protocol shall include all requirements in HSC, Chapter 692, §692.013 (Hospital Protocol).

(2) A hospital which performs organ transplants shall be a member of the Organ Procurement and Transplantation Network in accordance with 42 United States Code, §274 (Organ Procurement and Transplantation Network).

(c) All-hazard disaster preparedness.

(1) Definitions.

(A) Adult intensive care unit (ICU)--Can support critically ill/injured patients, including ventilator support.

(B) Burn or burn ICU--Either approved by the American Burn Association or self-designated. (These beds should not be included in other ICU bed counts.)

(C) Medical/surgical--Also thought of as "ward" beds.

(D) Negative pressure/isolation--Beds provided with negative airflow, providing respiratory isolation. Note: This value may represent available beds included in the counts of other types.

(E) Operating rooms--An operating room that is equipped and staffed and could be made available for patient care in a short period.

(F) Pediatric ICU--The same as adult ICU, but for patients 17 years and younger.

(G) Pediatrics--Ward medical/surgical beds for patients 17 years and younger.

(H) Physically available beds--Beds that are licensed, physically set up, and available for use. These are beds regularly maintained in the hospital for the use of patients, which furnish accommodations with supporting services (such as food, laundry, and housekeeping). These beds may or may not be staffed but are physically available.

(I) Psychiatric--Ward beds on a closed/locked psychiatric unit or ward beds where a patient will be attended by a sitter.

(J) Staffed beds--Beds that are licensed and physically available for which staff members are available to attend to the patient who occupies the bed. Staffed beds include those that are occupied and those that are vacant.

(K) Vacant/available beds--Beds that are vacant and to which patients can be transported immediately. These must include supporting space, equipment, medical material, ancillary and support services, and staff to operate under normal circumstances. These beds are licensed, physically available, and have staff on hand to attend to the patient who occupies the bed.

(2) A hospital shall adopt, implement, and enforce a written plan for all-hazard, natural or man-made, disaster preparedness for effective preparedness, mitigation, response, and recovery from disasters.

(3) The plan, which may be subject to review and approval by the department, shall be sent to the local disaster management authority.

(4) The plan shall:

(A) be developed through a joint effort of the hospital governing body, administration, medical staff, hospital personnel and emergency medical services partners;

(B) include the applicable information contained in the National Fire Protection Association 99, Standard for Health Care Facilities, 2002 edition, Chapter 12 (Health Care Emergency Management), published by the National Fire Protection Association (NFPA), and the State of Texas Emergency Management Plan. Information regarding the State of Texas Emergency Management Plan is available from the city or county emergency management coordinator. The NFPA document referenced in this section may be obtained by writing or calling the NFPA at the following address and telephone number: 1 Batterymarch Park, Post Office Box 9101, Quincy, Massachusetts 02269-9101, (800) 344-3555;

(C) contain the names and contact numbers of city and county emergency management officers and the hospital water supplier;

(D) be exercised at least annually and in conjunction with state and local exercises. Hospitals participating in an exercise or responding to a real life event shall develop an after action report (AAR) within 60 days. AARs shall be retained for at least three years and be available for review by the local emergency management authority and the department;

(E) include the methodology for notifying the hospital personnel and the local disaster management authority of an event that will significantly impact hospital operations;

(F) include evidence that the hospital has communicated prospectively with the local utility and phone companies

regarding the need for the hospital to be given priority for the restoration of utility and phone services and a process for testing internal and external communications systems regularly;

(G) include the use of a department approved process to update bed availability, as follows:

(i) as requested by the department during a public health emergency or state declared disaster; and

(ii) for the physically available beds and staffed beds that are vacant/available beds for the following bed types:

(I) adult ICU;

(II) burn or burn ICU;

(III) medical/surgical;

(IV) negative pressure/isolation;

(V) operating rooms;

(VI) pediatric ICU;

(VII) pediatrics; and

(VIII) psychiatric;

(iii) emergency department divert status;

(iv) for decontamination facility available; and

(v) for ventilators available;

(H) include at a minimum:

(i) a component for the reception, treatment, and disposition of casualties that can be used in the event that a disaster situation requires the hospital to accept multiple patients. This component shall include at a minimum:

(I) process, developed in conjunction with appropriate agencies, to allow essential healthcare workers and personnel to safely access their delivery care sites;

(II) procedures for the appropriate provision of personal protection equipment for and appropriate immunization of staff, volunteers, and staff families; and

(III) plan to provide food and shelter for staff and volunteers as needed throughout the duration of response;

(ii) an evacuation component that can be engaged in any emergency situation necessitating either a full or partial evacuation of the hospital. The evacuation component shall address at a minimum:

(I) activation, including who makes the decision to activate and how it is activated;

(II) when within control of the hospital, patient evacuation destination, including protocol to ensure that the patient destination is compatible to patient acuity and health care needs, plan for the order of removal of patients and planned route of movement, train and drill staff on the traffic flow and the movement of patients to a staging area, and room evacuation protocol;

(III) family/responsible party notification, including the procedure to notify patient emergency contacts of an evacuation and the patient's destination; and

(IV) transport of records and supplies, including the protocol for the transfer of patient specific medications and records to the receiving facility. These records shall include at a minimum: the patient's most recent physician's assessment, order sheet, medication administration record (MAR), and patient history with physical documentation. A weather-proof patient identification wrist band (or equivalent identification) must be intact on all patients.

(d) Voluntary paternity establishment services. A hospital that handles the birth of newborns must provide voluntary paternity establishment services in accordance with:

(1) the HSC, §192.012, Record of Acknowledgment of Paternity; and

(2) the rules of the Office of the Attorney General found at 1 TAC Chapter 55, Subchapter J (relating to Voluntary Paternity Acknowledgment Process).

(e) Harassment and abuse. A hospital shall adopt, implement and enforce a written policy for identifying and addressing instances of alleged verbal or physical abuse or harassment of hospital employees or contracted personnel by other hospital employees or contracted personnel or by a health care provider who has clinical privileges at the hospital.

(f) Information for parents of newborn children. A hospital that provides prenatal care to a pregnant woman during gestation or at delivery of an infant, shall adopt, implement and enforce written policies to ensure compliance with HSC, Chapter 161, Subchapter T, §161.501 (relating to Parenting and Postpartum Counseling Information).

(1) The policy shall require that the woman and the father of the infant, if possible, or another adult caregiver for the infant, be provided with a resource pamphlet which includes:

(A) information on professional organizations providing counseling and assistance relating to postpartum depression and other emotional trauma associated with pregnancy and parenting;

(B) information regarding the prevention of shaken baby syndrome, as specified under HSC, §167.501(a)(1)(B)(i) - (iv);

(C) a list of diseases for which a child is required by state law to be immunized and the appropriate schedule for the administration of those immunizations; and

(D) the appropriate schedule for follow-up procedure for newborn screening.

(2) The policy shall include a requirement that it be documented in the woman's record that the information was provided and that the documentation be maintained for at least five years.

(g) Abortion. A hospital that performs abortions shall adopt, implement and enforce policies to:

(1) ensure compliance with HSC, Chapter 171, Subchapters A and B (relating to Abortion and Informed Consent);

(2) ensure compliance with Occupations Code, §164.052(a)(19) (relating to Parental Consent for Abortion).

(h) Influenza and pneumococcal vaccine for elderly persons. The hospital shall adopt, implement and enforce a policy for providing influenza and pneumococcal vaccines for elderly persons. The policy shall:

(1) establish that an elderly person, defined as 65 years of age older, who is admitted to the hospital for a period of 24 hours or more, is informed of the availability of the influenza and pneumococcal vaccines, and, if they request the vaccine, is assessed to determine if receipt of the vaccine is in their best interest. If determined appropriate by the physician or other qualified medical personnel, the elderly person shall receive the vaccines prior to discharge from the hospital;

(2) include provisions that the influenza vaccine shall be made available in October and November, and if available, December, and pneumococcal vaccine shall be made available throughout the year;

(3) require that the person administering the vaccine ask the elderly patient if they are currently vaccinated against influenza or pneumococcal disease, assess potential contraindications, and then, if appropriate, administer the vaccine under approved hospital protocols; and

(4) address required documentation of the vaccination in the patient medical record.

(5) The department may waive requirements related to the administration of the vaccines based on established shortages of the vaccines.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on June 1, 2007.

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Lisa Hernandez
Deputy General Counsel
Department of State Health Services
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Proposal publication date: December 15, 2006
For further information, please call: (512) 458-7111 x6972

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SUBCHAPTER D. VOLUNTARY AGREEMENTS

25 TAC §133.61, §133.62

STATUTORY AUTHORITY

The repeals are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

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25 TAC §133.61, §133.62

STATUTORY AUTHORITY

The new sections are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

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SUBCHAPTER E. WAIVERS

25 TAC §133.81

STATUTORY AUTHORITY

The repeal is adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

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SUBCHAPTER E. WAIVER PROVISIONS

25 TAC §133.81

STATUTORY AUTHORITY

The new section is adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

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SUBCHAPTER F. INSPECTION AND INVESTIGATION PROCEDURES

25 TAC §133.101, §133.102

STATUTORY AUTHORITY

The repeals are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

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25 TAC §133.101, §133.102

STATUTORY AUTHORITY

The new sections are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

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SUBCHAPTER G. ENFORCEMENT

25 TAC §133.121, §133.122

STATUTORY AUTHORITY

The repeals are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

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25 TAC §133.121

STATUTORY AUTHORITY

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SUBCHAPTER H. FIRE PREVENTION AND SAFETY REQUIREMENTS

25 TAC §§133.141 - 133.143

STATUTORY AUTHORITY

The repeals are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

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25 TAC §§133.141 - 133.143

STATUTORY AUTHORITY

The new sections are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

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SUBCHAPTER I. PHYSICAL PLANT AND CONSTRUCTION REQUIREMENTS

25 TAC §§133.161 - 133.169

STATUTORY AUTHORITY

The repeals are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

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25 TAC §§133.161 - 133.169

STATUTORY AUTHORITY

The new sections are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

§133.162. New Construction Requirements.

(a) Hospital location. Any proposed new hospital shall be easily accessible to the community and to service vehicles such as delivery

trucks, ambulances, and fire protection apparatus. No building may be converted for use as a hospital which, because of its location, physical condition, state of repair, or arrangement of facilities, would be hazardous to the health and safety of the patients.

(1) Hazardous locations.

(A) Underground and above ground hazards. New hospitals or additions to existing hospitals shall not be constructed within 150 feet of easement boundaries or setbacks of hazardous underground locations including but not limited to liquid butane or propane, liquid petroleum or natural gas transmission lines, high pressure lines, and not within the easement of high voltage electrical lines.

(B) Fire hazards. New hospitals and additions to existing hospitals shall not be built within 300 feet of above ground or underground storage tanks containing liquid petroleum or other flammable liquids used in connection with a bulk plant, marine terminal, aircraft refueling, bottling plant of a liquefied petroleum gas installation, or near other hazardous or hazard producing plants.

(2) Undesirable locations.

(A) Nuisance producing sites. New hospitals shall not be located near nuisance producing industrial sites, feed lots, sanitary landfills, or manufacturing plants producing excessive noise or air pollution.

(B) Cemeteries. New hospitals shall not be located near a cemetery in a manner that allows direct view of the cemetery from patient windows.

(C) Flood plains.

(i) New construction. Construction of a new hospital is prohibited in a designated 100-year flood plain.

(ii) Previously licensed hospital. An existing building or a portion of an existing building located in a designated 100-year flood plain which was previously licensed as a hospital but has been vacated or used for purposes other than a hospital, will not be licensed as a hospital.

(iii) Existing hospital. Access and required functional hospital components shall be constructed above the designated flood plain in a new addition to an existing hospital located in a designated 100-year flood plain.

(D) Airports. Construction of new hospitals shall be avoided in close proximity to airports. When hospitals are proposed to be located near airports, recommendations of the Texas Aviation Authority and the Federal Aviation Authority shall apply. A hospital may not be constructed within a rectangular area formed by lines perpendicular to and two miles (10,560 feet) from each end of any runway and by lines parallel to and one-half mile (2,640 feet) from each side of any runway.

(b) Environmental considerations. Development of a hospital site and hospital construction shall be governed by state and local regulations and requirements with respect to the effect of noise and traffic on the community and the environmental impact on air and water.

(c) Hospital site.

(1) Paved roads and walkways. Paved roads shall be provided within the lot lines to provide access from public roads to the main entrance, emergency entrance, entrances serving community activities, and to service entrances, including loading and unloading docks for delivery trucks.

(A) Emergency entrance. Hospitals having an organized emergency services department shall have the emergency entrance well-marked to facilitate entry from the public roads or streets serving the site.

(B) Access to emergency department. Access to the emergency entrance shall not conflict with other vehicular traffic or pedestrian traffic and shall be located so as not to be compromised by floods.

(C) Pedestrian traffic. Finished surface walkways shall be provided for pedestrians.

(2) Parking. Off-street parking shall be available for visitors, employees, and staff. Parking structures directly accessible from a hospital shall be separated with two-hour fire rated noncombustible construction. When used as required means of egress for hospital occupants, parking structures shall comply with National Fire Protection Association 88A, Standard for Parking Structures, 2002 edition. This requirement does not apply to freestanding parking structures. All documents published by National Fire Protection Association (NFPA) as referenced in this section may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101 or (800) 344-3555.

(A) Number of parking places. In the absence of a formal parking study, one parking space shall be provided for each day shift employee plus one space for each patient bed. This ratio may be reduced in an area convenient to a public transportation system or to public parking facilities on the basis of a formal parking study. Parking facilities shall be increased accordingly when the size of existing facilities is increased.

(B) Additional parking. Additional parking shall be required to accommodate medical staff, outpatient and other services when such services are provided.

(C) Emergency and delivery parking. Separate parking facilities shall be provided for ambulances and delivery vehicles.

(d) Building design and construction requirements. Every building and every portion thereof shall be designed and constructed to sustain all dead and live loads in accordance with accepted engineering practices and standards and the local governing building codes. Where there is no local governing building code, the hospital shall be constructed in accordance with the International Building Code, 2003 edition, published by the International Code Council, 5203 Leesburg Pike, Falls Church, VA 22041, telephone (800) 786-4452.

(1) General architectural requirements. All new construction, including conversion of an existing building to a hospital, and establishing a separately licensed hospital in a building with an existing licensed hospital, shall comply with Chapter 18 of the National Fire Protection Association 101, Life Safety Code, 2003 edition (NFPA 101), and Subchapters H and I of this chapter (relating to Fire Prevention and Safety Requirements, and Physical Plant and Construction Requirements, respectively). Construction documents shall be submitted to the department in accordance with §133.167 of this title (relating to Preparation, Submittal, Review and Approval of Plans, and Retention of Records).

(A) Physical environment. A physical environment that protects the health and safety of patients, personnel, and the public shall be provided in each hospital. The physical premises of the hospital and those areas of the hospital's physical structure that are used by the patients (including all stairwells, corridors, and passageways) shall meet the local building and fire safety codes and Subchapters H and I of this chapter.

(B) Construction type. A hospital may occupy an entire building or a portion of a building, provided the hospital portion of the building is separated from the rest of the building in accordance with subparagraph (C) of this paragraph and the entire building or the hospital portion of the building complies with new construction requirements (type of construction permitted for hospitals by NFPA 101, §18.1.6.2), and the entire building is protected with a fire sprinkler system conforming with requirements of National Fire Protection Association 13, Standard for the Installation of Sprinkler Systems, 2002 Edition (NFPA 13).

(C) Separate buildings. Portions of a building divided horizontally with two-hour fire rated walls which are continuous (without offsets) from the foundation to above the roof shall be considered as a separate building. Communicating openings in the two-hour wall shall be limited to public spaces such as lobbies and corridors. All such openings shall be protected with self-closing one and one-half hour, Class B fire door assemblies.

(D) Design for the handicapped. Special considerations benefiting handicapped staff, visitors, and patients shall be provided. Each hospital shall comply with the Americans with Disabilities Act (ADA) of 1990, Public Law 101-336, 42 United States Code, Chapter 126, and Title 36 Code of Federal Regulations, Part 1191, Appendix A, Accessibility Guidelines for Buildings and Facilities, or 16 TAC Chapter 68, Texas Accessibility Standards (TAS), April 1, 1994 edition, issued by the Texas Department of Licensing and Regulation, under the Texas Architectural Barriers Act, Texas Government Code, Chapter 469.

(E) Patient safety. In developing construction documents for submission to the department in accordance with §133.167 of this title, the owner shall comply with the requirements of Health and Safety Code, Chapter 256, Safe Patient Handling and Movement Practices. Section 256.002(b)(8) requires a hospital's governing body to consider the feasibility of incorporating patient handling equipment or the physical space and construction design needed to incorporate that equipment at a later date.

(F) Other regulations. The more stringent standard, code or requirement shall apply when a difference in requirements for construction exists.

(G) Exceeding minimum requirements. Nothing in this subchapter shall be construed to prohibit a better type of building construction, more exits, or otherwise safer conditions than the minimum requirements specified in this subchapter.

(H) Equivalency. Nothing in this subchapter is intended to prevent the use of systems, methods, or devices of equivalent or superior quality, strength, fire resistance, effectiveness, durability, and safety to those prescribed by this subchapter, providing technical documentation which demonstrates equivalency is submitted to the department for approval.

(I) Freestanding buildings (not for patient use). Separate freestanding buildings for nonpatient use such as the heating plant, boiler plant, laundry, repair workshops, or general storage may be of unprotected noncombustible construction, protected noncombustible construction, or fire-resistive construction and be designed in accordance with other occupancy classifications requirements listed in NFPA 101.

(J) Freestanding buildings (for patient use other than sleeping). Buildings containing areas for patient use which do not contain patient sleeping areas and in which care or treatment is rendered to ambulatory inpatients who are capable of judgment and appropriate physical action for self-preservation under emergency conditions, may be classified as business or ambulatory care occupancies as listed in NFPA 101, Chapters 20 and 38, respectively, instead of hospital occupancy.

(K) Energy conservation. In new construction and in major alterations and additions to existing buildings and in new buildings, electrical and mechanical components shall be selected for efficient utilization of energy. Hospital construction shall be in accordance with the provisions of the Texas Building Energy Performance Standards, Health and Safety Code, Chapter 388.

(L) Heliports. Heliports located on hospital buildings or land used or intended to be used for landing and take off of helicopters shall comply with National Fire Protection Association 418, Standard for Heliports, and 2001 edition.

(2) General detail and finish requirements. Details and finishes in new construction projects, including additions and alterations, shall be in compliance with this paragraph, with NFPA 101, Chapter 18, with local building codes, and with any specific detail and finish requirements for the particular unit as contained in §133.163 of this title (relating to Spatial Requirements for New Construction).

(A) General detail requirements.

(i) Fire safety. Fire safety features, including compartmentation, means of egress, automatic extinguishing systems, inspections, smoking regulations, and other details relating to fire prevention and fire protection shall comply with §133.161 of this title (relating to Requirements for Buildings in Which Existing Licensed Hospitals Are Located), and NFPA 101, Chapter 18 requirements for hospitals. The Fire Safety Evaluation System for Health Care Occupancies contained in the National Fire Protection Association 101A, Alternative Approaches to Life Safety, 2001 edition, Chapter 3, shall not be used in new building construction, renovations or additions to existing hospitals.

(ii) Access to exits. Corridors providing access to all patient, diagnostic, treatment, and sleeping rooms and exits shall be at least eight feet in clear and unobstructed width (except as allowed by NFPA 101, §18.2.3.4, Exceptions 1 and 2), not less than seven feet six inches in height, and constructed in accordance with requirements listed in NFPA 101, §18.3.6.

(iii) Corridors in other occupancies. Public corridors in outpatient, administrative, and service areas which are designed to other than hospital requirements and are the required means of egress from the hospital shall be not less than five feet in width.

(iv) Encroachment into the means of egress. Items such as drinking fountains, telephone booths or stations, and vending machines shall be so located as to not project into and restrict exit corridor traffic or reduce the exit corridor width below the required minimum. Portable equipment shall not be stored so as to project into and restrict exit corridor traffic or reduce the exit corridor width below the required minimum.

(v) Doors in means of egress. All door leaves in the means of egress shall be not less than 44 inches wide or as otherwise permitted for hospitals by NFPA 101, §18.2.3.6.

(vi) Sliding doors. Horizontal sliding doors serving an occupant load of fewer than 10 shall be permitted. The area served by the door has no high hazard contents. The door is readily operable from either side without special knowledge or effort. The force required to operate the door in the direction of door travel is not more than 30 pounds per foot to set the door in motion and is not more than 15 pounds per foot to close the door or open in the minimum required width. The door assembly complies with any required fire protection

rating, and, where rated, is self-closing or automatic closing. The sliding doors opening to the egress corridor doors shall have a latch or other mechanism that ensures that the doors will not rebound into a partially open position if forcefully closed. The sliding doors may have breakaway provisions and shall be installed to resist passage of smoke. The latching sliding panel shall have a minimum clear opening of 41.5 inches in the fully open position. The fixed panels may have recessed tracks.

(vii) Control doors. Designs that include cross-corridor control doors should be avoided. When unavoidable, cross-corridor control doors shall consist of two 44-inch wide leaves which swing in a direction opposite from the other, or of the double acting type. Each door leaf shall be provided with a view window.

(viii) Emergency access. Rooms containing bathtubs, showers, and water closets, intended for patient use shall be provided with at least one door having hardware which will permit access from the outside in any emergency. Door leaf width of such doors shall not be less than 36 inches.

(ix) Obstruction of corridors. All doors which swing towards the corridor must be recessed. Corridor doors to rooms not subject to occupancy (any room that you can walk into and close the door behind you is considered occupiable) may swing into the corridor, provided that such doors comply with the requirements of NFPA 101, §7.2.1.4.4.

(x) Stair landing. Doors shall not open immediately onto a stair without a landing. The landing shall be 44 inches deep or have a depth at least equal to the door width, whichever is greater.

(xi) Doors to rooms subject to occupancy. All doors to rooms subject to occupancy shall be of the swing type except that horizontal sliding doors complying with the requirements of NFPA 101, §18.2.2.2.9 are permitted. Door leaves to rooms subject to occupancy shall not be less than 36 inches wide.

(xii) Operable windows and exterior doors. Windows that can be opened without tools or keys and outer doors without automatic closing devices shall be provided with insect screens.

(xiii) Glazing. Glass doors, lights, sidelights, borrowed lights, and windows located within 12 inches of a door jamb or with a bottom-frame height of less than 18 inches and a top-frame height of more than 36 inches above the finished floor which may be broken accidentally by pedestrian traffic shall be glazed with safety glass or plastic glazing material that will resist breaking and will not create dangerous cutting edges when broken. Similar materials shall be used for wall openings in activity areas such as recreation and exercise rooms, unless otherwise required for fire safety. Safety glass, tempered or plastic glazing materials shall be used for shower doors and bath enclosures, interior windows and doors. Plastic and similar materials used for glazing shall comply with the flame spread ratings of NFPA 101, §18.3.3.

(xiv) Fire doors. All fire doors shall be listed by an independent testing laboratory and shall meet the construction requirements for fire doors in National Fire Protection Association 80, Standard for Fire Doors and Fire Windows, 1999 edition. Reference to a labeled door shall be construed to include labeled frame and hardware.

(xv) Grab bars. Grab bars shall be provided at patient toilets, showers and tubs. The bars shall be one and one-half inches in diameter, shall have either one and one-fourth or one and one-half inches clearance to walls, and shall have sufficient strength and anchorage to sustain a concentrated vertical or horizontal load of 250 pounds. Grab bars are not permitted at bathing and toilet fixtures in mental health and chemical dependency units unless designed and installed to eliminate the possibility of patients harming themselves. Grab bars intended for use by the disabled shall also comply with ADA requirements.

(xvi) Soap dishes. Soap dishes shall be provided at all showers and bathtubs.

(xvii) Hand washing facilities. Location and arrangement of fittings for hand washing facilities shall permit their proper use and operation. Hand washing fixtures with hands-free operable controls shall be provided within each workroom, examination, and treatment room. Hands-free includes blade-type handles, and foot, knee, or sensor operated controls. Particular care shall be given to the clearances required for blade-type operating handles. Lavatories and hand washing facilities shall be securely anchored to withstand an applied vertical load of not less than 250 pounds on the front of the fixture. In addition to the specific areas noted, hand washing facilities shall be provided and conveniently located for staff use throughout the hospital where patient care contact occurs and services are provided.

(xviii) Soap dispensers. A liquid or foam soap dispenser shall be located at each hand washing facility.

(xix) Alcohol-based hand rubs. Alcohol-based hand rubs (ABHRs) are considered flammable. When used, the ABHRs shall meet the following requirements:

(I) The dispensers may be installed in a corridor so long as the corridor width is six feet or greater. The dispensers shall be installed at least four feet apart.

(II) The maximum individual dispenser fluid capacity is 1.2 liters for dispensers in rooms, corridors, and areas open to corridors, and 2.0 liters for dispensers in suites of rooms.

(III) The dispensers shall not be installed over or directly adjacent to electrical outlets and switches.

(IV) Dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

(V) Each smoke compartment may contain a maximum aggregate of 10 gallons of ABHR solution in dispensers and a maximum of five gallons in storage.

(xx) Hand drying. Provisions for hand drying shall be included at all hand washing facilities except scrub sinks. There shall be hot air dryers or individual paper or cloth units enclosed in such a way as to provide protection against dust or soil and ensure single-unit dispensing.

(xxi) Mirrors. Mirrors shall not be installed at hand washing fixtures where asepsis control and sanitation requirements would be lessened by hair combing. Mirrors may be installed in patient rooms, patient toilet rooms, lockers, and public toilet rooms.

(xxii) Ceiling heights. The minimum ceiling height shall be seven feet six inches with the following exceptions.

(I) Boiler rooms. Boiler rooms shall have ceiling clearances not less than two feet six inches above the main boiler header and connecting piping.

(II) Rooms with ceiling-mounted equipment. Rooms containing ceiling-mounted equipment shall have the ceiling height clearance increased to accommodate the equipment or fixtures.

(III) Overhead clearance. Suspended tracks, rails, pipes, signs, lights, door closers, exit signs, and other fixtures that protrude into the path of normal traffic shall not be less than six feet eight inches above the finished floor.

(xxiii) Areas producing impact noises. Recreation rooms, exercise rooms, and similar spaces where impact noises may be generated shall not be located directly over patient bed area or operating rooms unless special provisions are made to minimize noise.

(xxiv) Noise reduction. Noise reduction criteria in accordance with the Table 1 in §133.169(a) of this title (relating to Tables) shall apply to partitions, floor, and ceiling construction in patient areas.

(xxv) Rooms with heat-producing equipment. Rooms containing heat-producing equipment such as heater rooms, laundries, etc. shall be insulated and ventilated to prevent any occupied floor surface above from exceeding a temperature differential of 10 degrees Fahrenheit above the ambient room temperature.

(xxvi) Chutes. Linen and refuse chutes shall comply with the requirements of National Fire Protection Association 82, Standard on Incinerators, Waste and Linen Handling Systems and Equipment, 2004 edition, and NFPA 101, §18.5.4.

(xxvii) Thresholds and expansion joint covers. Thresholds and expansion joint covers shall be flush or not more than one-half inch above the floor surface to facilitate the use of wheelchairs and carts. Expansion and seismic joints shall be constructed to restrict the passage of smoke and fire and shall be listed by a nationally recognized testing laboratory.

(xxviii) Housekeeping room.

(I) In addition to the housekeeping room(s) required in certain departments, sufficient housekeeping rooms shall be provided throughout the hospital as required to maintain a clean and sanitary environment.

(II) Each housekeeping room shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies.

(B) General finish requirements.

(i) Cubicle curtains and draperies.

(I) Cubicle curtains, draperies and other hanging fabrics shall be noncombustible or flame retardant and shall pass both the small scale and the large-scale tests of National Fire Protection Association 701, Standard Methods of Fire Tests for Flame-Resistant Textiles and Films, 1999 edition. Copies of laboratory test reports for installed materials shall be submitted to the department at the time of the final construction inspection.

(II) Cubicle curtains shall be provided to assure patient privacy.

(ii) Flame spread, smoke development and noxious gases. Flame spread and smoke developed limitations of interior finishes shall comply with Table 2 of §133.169(b) of this title and NFPA 101, §10.2. The use of materials known to produce large or concentrated amounts of noxious or toxic gases shall not be used in exit accesses or in patient areas. Copies of laboratory test reports for installed materials tested in accordance with National Fire Protection Association 255, Standard Method of Test of Surface Burning Characteristics of Building Materials, 2000 edition, and National Fire Protection Association 258, Standard Research Test Method for Determining Smoke Generation of Solid Materials, 2001 edition, shall be provided.

(iii) Floor finishes. Flooring shall be easy to clean and have wear resistance appropriate for the location involved. Floors that are subject to traffic while wet (such as shower and bath areas, kitchens, and similar work areas) shall have a nonslip surface. In all areas frequently subject to wet cleaning methods, floor materials shall not be physically affected by germicidal and cleaning solutions. The following are acceptable floor finishes:

(I) painted concrete;

(II) vinyl and vinyl composition tiles and sheets;

(III) monolithic or seamless flooring. Where required, seamless flooring shall be impervious to water, coved and installed integral with the base, tightly sealed to the wall, and without voids that can harbor insects or retain dirt particles. The base shall not be less then six inches in height. Welded joint flooring is acceptable;

(IV) ceramic and quarry tile;

(V) wood floors. Wood floors subject to frequent cleaning methods shall be avoided. When wood floors are used, the floor shall be tightly sealed, without voids and the joints shall be impervious to water;

(VI) carpet flooring. Carpeting installed in intensive care units, nurseries, patient rooms and similar patient care areas shall be treated to prevent bacterial and fungal growth;

(VII) terrazzo; and

(VIII) poured in place floors.

(iv) Wall finishes. Wall finishes shall be smooth, washable, moisture resistant, and cleanable by standard housekeeping practices. Wall finishes shall comply with requirements contained in Table 2 of §133.169(b) of this title, and NFPA 101, §18.3.3.

(I) Wall finishes shall be water-resistant in the immediate area of plumbing fixtures.

(II) Wall finishes subject to frequent wet cleaning methods shall be impervious to water, tightly sealed and without voids.

(v) Floor, wall and ceiling penetrations. Floor, wall and ceiling penetrations by pipes, ducts, and conduits or any direct openings shall be tightly sealed to minimize entry of dirt particles, rodents and insects. Joints of structural elements shall be similarly sealed.

(vi) Ceiling types. Ceilings which are a part of a rated roof/ceiling assembly or a floor/ceiling assembly shall be constructed of listed components and installed in accordance with the listing. Three types of ceilings that are required in various areas of the hospital are:

(I) Ordinary ceilings. Ceilings such as acoustical tiles installed in a metal grid which are dry cleanable with equipment used in daily housekeeping activities such as dusters and vacuum cleaners.

(II) Washable ceilings. Ceilings that are made of washable, smooth, moisture impervious materials such as painted lay-in gypsum wallboard or vinyl faced acoustic tile in a metal grid.

(III) Monolithic ceilings. Ceilings which are monolithic from wall to wall (painted solid gypsum wallboard), smooth and without fissures, open joints, or crevices and with a washable and moisture impervious finish.

(vii) Special construction. Special conditions may require special wall and ceiling construction for security in areas such as storage of controlled substances and areas where patients are likely to attempt suicide or escape.

(viii) Flammable anesthetizing locations. Flammable anesthetic locations in which flammable anesthetic agents are stored or administered shall comply with Annex E of the National

Fire Protection Association 99, Standard for Health Care Facilities, 2002 edition (NFPA 99).

(ix) Materials finishes. Materials known to produce noxious gases when burned shall not be used for mattresses, upholstery, and wall finishes.

(x) Signage. A sign shall be posted at the entrance to each toilet/restroom to identify the facility for public, staff or patient use. Signs are not required for patient room bathrooms.

(3) General mechanical requirements. This paragraph contains common requirements for mechanical systems; steam and hot and cold water systems; air conditioning, heating and ventilating systems; plumbing fixtures; piping systems; and thermal and acoustical insulation. The hospital shall comply with the requirements of this paragraph and any specific mechanical requirements for the particular unit of the hospital in accordance with §133.163 of this title.

(A) Equipment location. When mechanical equipment is exposed to weather, it shall be protected by weatherproof construction or weather protected.

(B) Vibration isolation. Mechanical equipment shall be mounted on vibration isolators as required to prevent unacceptable structure-borne vibration. Ducts, pipes, etc. connected to mechanical equipment which is a source of vibration shall be isolated from the equipment with vibration isolators.

(C) Performance and acceptance. Prior to completion and acceptance of the facility, all mechanical systems shall be tested, balanced, and operated to demonstrate to the design engineer or his representative that the installation and performance of these systems conform to the requirements of the plans and specifications.

(i) Material lists. Upon completion of the contract, the owner shall be provided with parts lists and procurement information with numbers and description for each piece of equipment.

(ii) Instructions. Upon completion of the contract, the owner shall be provided with instructions in the operational use of systems and equipment as required.

(D) Heating, ventilating and air conditioning (HVAC) systems. All HVAC systems shall comply with and shall be installed in accordance with the requirements of National Fire Protection Association 90A, Standard for the Installation of Air Conditioning and Ventilating Systems, 2002 edition, (NFPA 90A), NFPA 99, Chapter 6, the requirements contained in this subparagraph, and the specific requirements for a particular unit in accordance with §133.163 of this title.

(i) General ventilation requirements. All rooms and areas in the hospital listed in Table 3 of §133.169(c) of this title shall have provision for positive ventilation. Fans serving exhaust systems shall be located at the discharge end and shall be conveniently accessible for service. Exhaust systems may be combined, unless otherwise noted, for efficient use of recovery devices required for energy conservation. The ventilation rates shown in Table 3 of §133.169(c) of this title shall be used only as minimum requirements since they do not preclude the use of higher rates that may be appropriate. Supply air to the building and exhaust air from the building shall be regulated to provide a positive pressure within the building with respect to the exterior.

(I) Cost reduction methods. To reduce utility costs, facility design may utilize energy conserving procedures including recovery devices, variable air volume, load shedding, systems shutdown or reduction of ventilation rates (when specifically permitted) in certain areas when unoccupied. In no case shall patient care be jeopardized.

(II) Economizer cycle. Mechanical systems shall be arranged to take advantage of outside air conditions by using an economizer cycle when appropriate to reduce heating and cooling systems loads. Innovative design that provides for additional energy conservation while meeting the intent of this section for acceptable patient care may be presented to the department for consideration.

(III) Outside air intake locations. Outside air intakes shall be located at least 25 feet from exhaust outlets of ventilating systems, combustion equipment stacks, medical-surgical vacuum systems, plumbing vents, or areas which may collect vehicular exhaust or other noxious fumes. (Prevailing winds and proximity to other structures may require more stringent requirements). Plumbing and vacuum vents that terminate five feet above the level of the top of the air intake may be located as close as 10 feet.

(IV) Low air intake location limit. The bottom of outside air intakes serving central systems shall be located as high as practical but at least six feet above ground level, or if installed above the roof, three feet above the roof level.

(V) Contaminated air exhaust outlets. Exhaust outlets from areas (kitchen hoods, etc.) that exhaust contaminated air shall be above the roof and be arranged to exhaust upward unless the air has been treated by an appropriate means where sidewall exhaust will be allowed. Ethylene oxide sterilizers shall be terminated above the roof and be arranged to exhaust upward.

(VI) Directional air flow. Ventilation systems shall be designed and balanced to provide directional flow as shown in Table 3 of §133.169(c) of this title. For reductions and shutdown of ventilation systems when a room is unoccupied, the provisions in Note 4 of Table 3 of §133.169(c) of this title shall be followed.

(VII) Areas requiring fully ducted systems. Fully ducted supply, return and exhaust air for HVAC systems shall be provided for all critical care areas, sensitive care areas, all patient care areas, all areas requiring a sterile regimen, storage rooms, food preparation areas, and where required for fire safety purposes. Combination systems, utilizing both ducts and plenums for movement of air in these areas shall not be permitted.

(VIII) Ventilation start-up requirements. Air handling systems shall not be started or operated without the filters installed in place. This includes the 90% and 99.97% efficiency filters where required. Ducts shall be cleaned thoroughly and throughout by a certified air duct cleaning contractor when the air handling systems have been operating without the required filters in place. When ducts are determined to be dirty or dusty, the department will require a written report assuring cleanliness of duct and clean air quality.

(IX) Humidifier location. When duct humidifiers are located upstream of the final filters, they shall be located at least 15 feet from the filters. Ductwork with duct-mounted humidifiers shall be provided with a means of removing water accumulation. An adjustable high-limit humidistat shall be located downstream of the humidifier to reduce the potential of condensation inside the duct. All duct take-offs should be sufficiently downstream of the humidifier to ensure complete moisture absorption. Reservoir-type water spray or evaporative pan humidifiers shall not be used.

(ii) Filtration requirements. All central air handling systems serving patient care areas, including nursing unit corridors, shall be equipped with filters having efficiencies equal to, or greater than, those specified in Table 4 of §133.169(d) of this title. Filter efficiencies shall be average efficiencies tested in accordance with American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE), Inc., Standard 52.2, 1999 edition, Method of Testing Gen-

eral Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size. All joints between filter segments, and between filter segments and the enclosing ductwork, shall have gaskets and seals to provide a positive seal against air leakage. Air handlers serving more than one room shall be considered as central air handlers. All documents published by ASHRAE as referenced in this section may be obtained by writing or calling the ASHRAE, Inc. at the following address or telephone number: ASHRAE, Inc., 1791 Tullie Circle, N. E., Atlanta, GA 30329; telephone (404) 636-8400.

(I) Filtration requirements for air handling units serving single rooms requiring asepsis control. Dedicated air handlers serving only one room where asepsis control is required, such as, but not limited to, operating rooms, delivery rooms, special procedure rooms, and nurseries shall be equipped with filters having efficiencies equal to, or greater than, those specified for patient care areas in Table 4 of §133.169(d) of this title.

(II) Filtration requirements for air handling units serving other single rooms. Dedicated air handlers serving all other single rooms shall be equipped with nominal filters installed at the return air system.

(III) Location of multiple filters. Where two filter beds are required by Table 4 of §133.169(d) of this title, filter bed number one shall be located upstream of the air conditioning equipment, and filter bed number two shall be downstream of the supply air blowers and cooling and heating coils.

(IV) Location of single filters. Where only one filter bed is required by Table 4 of §133.169(d) of this title, it shall be located upstream of the supply fan. Filter frames shall be durable and constructed to provide an airtight fit with the enclosing ductwork.

(V) Pressure monitoring devices. A manometer or draft gauge shall be installed across each filter bed having a required efficiency of 75% or more including hoods requiring high efficiency particulate air (HEPA) filters.

(iii) Thermal and acoustical insulation for air handling systems. Asbestos insulation shall not be used.

(I) Thermal duct insulation. Air ducts and casings with outside surface temperature below ambient dew point or temperature above 80 degrees Fahrenheit shall be provided with thermal insulation.

(II) Insulation in air plenums and ducts. Linings in air ducts and equipment shall meet the Erosion Test Method described in Underwriters Laboratories (UL), Inc., Standard Number 181 (relating to Factory-Made Duct Materials and Air Duct Connectors), April 4, 1996 edition. This document may be obtained from the Underwriters Laboratories, Inc., 333 Pfingsten Road, Northbrook, IL 60062-2096.

(III) Insulation flame spread and smoke developed ratings. Interior and exterior insulation, including finishes and adhesives on the exterior surfaces of ducts and equipment, shall have a flame spread rating of 25 or less and a smoke developed rating of 50 or less as required by NFPA 90A, Chapters 4 and 5.

(IV) Linings and acoustical traps. Duct lining and acoustical traps exposed to air movement shall not be used in ducts serving critical care areas. This requirement shall not apply to mixing boxes and acoustical traps that have approved nonabrasive coverings over such linings.

(V) Frangible insulation. Insulation of soft and spray-on types shall not be used where it is subject to air currents or mechanical erosion or where loose particles may create a maintenance problem.

(VI) Existing duct linings. Internal linings shall not be used in ducts, terminal boxes, or other air system components supplying operating rooms, delivery rooms, birthing rooms, labor rooms, recovery rooms, nurseries, trauma rooms, isolation rooms, and intensive care units unless terminal filters of at least 90% efficiency are installed downstream of linings.

(iv) Ventilation for anesthetizing locations. Ventilation for anesthetizing locations, as defined in NFPA 99, §3.3, shall comply with NFPA 99, §13.4.1.2, and any specific ventilation requirements for the particular unit in accordance with §133.163 of this title.

(I) Smoke removal systems for windowless anesthetizing locations. Smoke removal systems shall be provided in all windowless anesthetizing locations in accordance with NFPA 99, §6.4.1.2.

(II) Smoke removal systems for surgical suites. Smoke removal systems shall be provided in all surgical suites in accordance with NFPA 99, §6.4.1.3.

(III) Smoke exhaust grilles. Exhaust grilles for smoke evacuation systems shall be ceiling-mounted or wall-mounted within 12 inches of the ceiling.

(v) Location of return and exhaust air devices. The bottoms of wall-mounted return and exhaust air openings shall be at least four inches above the floor. Return air openings located less than six inches above the floor shall be provided with nominal filters. All exhaust air openings and return air openings located higher than six inches but less than seven feet above the floor shall be protected with grilles or screens having openings through which a one-half inch sphere will not pass.

(vi) Ray protection. Ducts which penetrate construction intended for X-ray or other ray protection shall not impair the effectiveness of the protection.

(vii) Fire damper requirements. Fire dampers shall be located and installed in all ducts at the point of penetration of a required two-hour or higher fire rated wall or floor in accordance with the requirements of NFPA 101, §18.5.2.

(viii) Smoke damper requirements. Smoke dampers shall be located and installed in accordance with the requirements of NFPA 101, §18.3.7.3, and NFPA 90A, Chapter 5.

(I) Fail-safe installation. Smoke dampers shall close on activation of the fire alarm system by smoke detectors installed and located as required by National Fire Protection Association 72, National Fire Alarm Code, 2002 edition (NFPA 72), Chapter 8; NFPA 90A, Chapter 6; and NFPA 101, §18.3.7; the fire sprinkler system; and upon loss of power. Smoke dampers shall not close by fan shutdown alone unless it is a part of an engineered smoke removal system.

(II) Interconnection of air handling fans and smoke dampers. Air handling fans and smoke damper controls may be interconnected so that closing of smoke dampers will not damage the ducts.

(III) Frangible devices. Use of frangible devices for shutting smoke dampers is not permitted.

(ix) Acceptable damper assemblies. Only fire damper and smoke damper assemblies integral with sleeves and listed for the intended purpose shall be acceptable.

(x) Duct access doors. Unobstructed access to duct openings in accordance with NFPA 90A, §4.3.4, shall be provided in ducts within reach and sight of every fire damper, smoke damper and smoke detector. Each opening shall be protected by an internally insulated door which shall be labeled externally to indicate the fire protection device located within.

(xi) Restarting controls. Controls for restarting fans may be installed for convenient fire department use to assist in evacuation of smoke after a fire is controlled, provided that provisions are made to avoid possible damage to the system because of closed dampers. To accomplish this, smoke dampers shall be equipped with remote control devices.

(xii) Make-up air. If air supply requirements in Table 3 of §133.169(c) of this title do not provide sufficient air for use by exhaust hoods and safety cabinets, filtered make-up air shall be ducted to maintain the required air flow direction in that room. Make-up systems for hoods shall be arranged to minimize short circuiting of air and to avoid reduction in air velocity at the point of contaminant capture.

(4) General piping systems and plumbing fixture requirements. All piping systems and plumbing fixtures shall be designed and installed in accordance with the requirements of the National Standard Plumbing Code Illustrated published by the National Association of Plumbing-Heating-Cooling Contractors (PHCC), 2003 edition, and this paragraph. The National Standard Plumbing Code may be obtained by writing or calling the PHCC at the following address or telephone number: Plumbing-Heating-Cooling Contractors, P.O. Box 6808, Falls Church, VA 22046; telephone (800) 533-7694.

(A) Piping systems.

(i) Water supply systems. Water service pipe to point of entrance to the building shall be brass pipe, copper tube (not less than type M when buried directly), copper pipe, cast iron water pipe, galvanized steel pipe, or approved plastic pipe. Domestic water distribution system piping within buildings shall be brass pipe, copper pipe, copper tube, or galvanized steel pipe. Piping systems shall be designed to supply water at sufficient pressure to operate all fixtures and equipment during maximum demand.

(I) Valves. Each water service main, branch main, riser, and branch to a group of fixtures shall be equipped with accessible and readily identifiable shutoff valves. Stop valves shall be provided at each fixture.

(II) Backflow preventers. Backflow preventers (vacuum breakers) shall be installed on hose bibbs, laboratory sinks, janitor sinks, bedpan-flushing attachments, autopsy tables, and on all other fixtures to which hoses or tubing can be attached.

(III) Flushing valves. Flush valves installed on plumbing fixtures shall be of a quiet operating type, equipped with silencers.

(IV) Capacity of water heating equipment. Water heating equipment shall have sufficient capacity to supply water for clinical, dietary and laundry use at the temperatures and amounts specified in Table 5 of §133.169(e) of this title.

(V) Water temperature measurements. Water temperatures shall be measured at hot water point of use or at the inlet to processing equipment.

(VI) Water storage tanks. Domestic water storage tank(s) shall be fabricated of corrosion-resistant metal or lined with noncorrosive material. When potable water storage tanks (hot and cold) are used, the water shall be used and replenished. Water shall not be stored in tanks for future use unless the water is tested weekly for contaminates/bacteria.

(VII) Hot water distribution. Water distribution systems shall be arranged to provide hot water at each hot water outlet at all times.

(VIII) Emergency water supply. Emergency potable water storage facilities shall be provided. The storage capacity shall not be less than 500 gallons or 12 gallons per licensed patient bed, whichever is greater. Capacity of hot water storage tanks may be included as part of the required emergency water capacity when valves and piping systems are arranged to make this water available at all times. When bottle water is used in lieu of water storage facilities, the hospital shall maintain and ensure the required amount of bottled water supply on hand at all times, maintain an inventory record which reflects the rotation and replacement of expired bottled water, and have adequate storage space on site that is readily accessible by staff in the event of an emergency. The hospital shall ensure the continued availability and delivery of bottled water until the emergency situation has concluded.

(IX) Purified water supply system. Purified water distribution system piping shall be task specific and include, but not necessarily be limited to, Polypropylene (PP), Polyvinylidene fluoride (PVDF) or Polyvinyl Chloride (PVC) pipe. Final installed purified water system piping assemblies shall be UL approved and fully comply with applicable American Society for Testing and Materials (ASTM) Fire Resistant/Smoke Density requirements. The applicable documents are available from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428-2959.

(X) Dead-end piping. Dead-end piping (risers with no flow, branches with no fixture) shall not be installed. In any renovation work, dead-end piping shall be removed. Empty risers, mains and branches installed for future use are permitted.

(ii) Fire sprinkler systems. Fire sprinkler systems shall be provided in hospitals as required by NFPA 101, §18.3.5. All fire sprinkler systems shall be designed, installed, and maintained in accordance with the requirements of NFPA 13, and shall be certified as required by §133.168(c)(1)(C) of this title (relating to Construction, Inspections, and Approval of Project).

(iii) Nonflammable medical gas and clinical vacuum systems. Nonflammable medical gas and clinical vacuum system installations shall be designed, installed and certified in accordance with the requirements of NFPA 99, §5.1 for Level I systems and the requirements of this clause.

(I) Outlets. Nonflammable medical gas and clinical vacuum outlets shall be provided in accordance with Table 6 of §133.169(f) of this title.

(II) Installer qualifications. All installations of the medical gas piping systems shall be done only by, or under the direct supervision of a holder of a master plumber license or a journeyman plumber license with a medical gas piping installation endorsement issued by the Texas State Board of Plumbing Examiners.

(III) Installer tests. Prior to closing of walls, the installer shall perform an initial pressure test, a blowdown test, a secondary pressure test, a cross-connection test, and a purge of the piping system as required by NFPA 99.

(IV) Qualifications for conducting verification tests and inspections. Verification testing shall be performed and inspected by a party, other than the installer, installing contractor, or material vendor. Testing shall be conducted by a registered medical

gas system verifier and technically competent and experienced in the field of medical gas and vacuum pipeline testing and meeting the requirements of the American Society of Safety Engineers (ASSE) Personnel Standard 6030, Professional Qualifications Standard for Medical Gas Systems. The document published by ASSE Personnel Standard 6030, Professional Qualifications Standard for Medical Gas Systems as referenced in this rule may be obtained by writing or calling The American Society of Safety Engineers (ASSE) at ASSE International Office, 901 Canterbury, Suite A, Westlake, Ohio 44145, telephone (440) 885-3040.

(V) Verification tests. Upon completion of the installer inspections and tests and after closing of walls, verification tests of the medical gas piping systems, the warning system, and the gas supply source shall be conducted. The verification tests shall include a cross-connection test, valve test, flow test, piping purge test, piping purity test, final tie-in test, operational pressure tests, and medical gas concentration test.

(VI) Verification test requirements. Verification tests of the medical gas piping system and the warning system shall be performed on all new piped medical gas systems, additions, renovations, or repaired portions of an existing system. All systems that are breached and components that are added, renovated, or replaced shall be inspected and appropriately tested. The breached portions of the systems subject to inspection and testing shall be all of the new and existing components in the immediate zone or area located upstream of the point or area of intrusion and downstream to the end of the system or a properly installed isolation valve.

(VII) Warning system verification tests. Verification tests of piped medical gas systems shall include tests of the source alarms and monitoring safeguards, master alarm systems, and the area alarm systems.

(VIII) Source equipment verification tests. Source equipment verification tests shall include medical gas supply sources (bulk and manifold) and the compressed air source systems (compressors, dryers, filters, and regulators).

(IX) Hospital responsibility. Before new piped medical gas systems, additions, renovations, or repaired portions of an existing system are put into use, the hospital shall be responsible for ensuring that the gas delivered at the outlet is the gas shown on the outlet label and that the proper connecting fittings are checked against their labels.

(X) Written certification. Upon successful completion of all verification tests, written certification for affected piped medical gas systems and piped medical vacuum systems including the supply sources and warning systems shall be provided by a party technically competent and experienced in the field of medical gas pipeline testing stating that the provisions of NFPA 99 have been adhered to and systems integrity has been achieved. The written certification shall be submitted directly to the hospital and the installer. A copy shall be forwarded to the department by the hospital.

(XI) Documentation of medical gas and clinical vacuum outlets. Documentation of the installed, modified, extended or repaired medical gas piping system shall be submitted to the department by the same party certifying the piped medical gas systems. The number and type of medical gas outlets (oxygen, vacuum, medical air, nitrogen, nitrous oxide, etc.) shall be documented and arranged tabularly by room numbers and room types.

(iv) Medical gas storage facilities. Main storage of medical gases may be outside or inside the hospital in accordance with NFPA 99, §5.1. Provision shall be made for additional separate storage of reserve gas cylinders necessary to complete at least one day's procedures.

(v) Multiple gas outlets on one medical gas outlet. Y-connections, "twinning," or other similar devices shall not be used on any medical gas outlet.

(vi) Waste anesthetic gas disposal (WAGD) systems. Each space routinely used for administering inhalation anesthesia shall be provided with a WAGD system as required by NFPA 99, §5.1.3.7.

(vii) Steam and hot water systems.

(I) Boilers. Boilers shall have the capacity, based upon the net ratings as published in The I-B-R Ratings Book for Boilers, Baseboard Radiation and Finned Tube (commercial) by the Hydronics Institute Division of GAMA, to supply the normal requirements of all systems and equipment. The number and arrangement of boilers shall be such that, when one boiler breaks down or routine maintenance requires that one boiler be temporarily taken out of service, the capacity of the remaining boiler(s) shall be sufficient to provide hot water service for clinical, dietary, and patient use, steam for sterilization and dietary purposes, and heating for operating, delivery, emergency, labor, recovery, intensive care, nursery, treatment, and general patient rooms. However, reserve capacity for space heating of noncritical care areas (e.g. general patient rooms and administrative areas) is not required in geographical areas where a design dry bulb temperature equals 25 degrees Fahrenheit or higher as based on the 99% design value shown in the Handbook of Fundamentals, 2005 edition, published by ASHRAE, Inc. The document published by the Hydronics Institute Division of GAMA as referenced in this rule may be obtained by writing or calling the Hydronics Institute Division of GAMA at 35 Russo Place, P.O. Box 218, Berkeley Heights, N.J. 07922, telephone (908) 464-8200.

(II) Boiler accessories. Boiler feed pumps, heating circulating pumps, condensate return pumps, and fuel oil pumps shall be connected and installed to provide normal and standby service.

(III) Valves. Supply and return mains and risers of cooling, heating, and process steam systems shall be valved to isolate the various sections of each system. Each piece of equipment shall be valved at the supply and return ends except that vacuum condensate returns need not be valved at each piece of equipment.

(IV) Hot water distribution systems. Hot water distribution systems for patient care areas shall be under constant recirculation to provide continuous hot water at each hot water outlet. Nonrecirculated fixtures branch piping shall not exceed 25 feet in length. Water temperature is measured at the point of use or inlet to the equipment. Tankless water system may be used at point of use.

(V) Domestic hot water system. The domestic hot water system shall make provisions to limit the amount of Legionella bacteria and opportunistic waterborne pathogens.

(viii) Drainage systems.

(I) Above ground piping. Soil stacks, drains, vents, waste lines, and leaders installed above ground within buildings shall be drain-waste-vent (DWV) weight or heavier and shall be: copper pipe, copper tube, cast iron pipe, or galvanized iron pipe.

(II) Underground piping. All underground building drains shall be: cast iron soil pipe, hard temper copper tube (DWV or heavier), acrylonitrile-butodiene-styrene (ABS) plastic pipe (DWV Schedule 40 or heavier), polyvinyl chloride (PVC) plastic pipe (DWV Schedule 40 or heavier), or extra strength vitrified clay pipe (VCP) with compression joints or couplings with at least 12 inches of earth cover.

(III) Drains for chemical wastes. Separate drainage systems for chemical wastes (acids and other corrosive materials) shall be provided. Materials acceptable for chemical waste drainage systems shall include chemically resistant glass pipe, high silicone content cast iron pipe, VCP, plastic pipe, or plastic lined pipe.

(ix) Thermal insulation for piping systems and equipment. Insulation shall be provided for the following:

(I) boilers, smoke breeching, and stacks;

(II) steam supply and condensate return piping;

(III) hot water piping and all hot water heaters, generators, converters, and storage tanks;

(IV) chilled water, refrigerant, other process piping, equipment operating with fluid temperatures below ambient dew point, and water supply and drainage piping on which condensation may occur. Insulation on cold surfaces shall include an exterior vapor barrier;

(V) other piping, ducts, and equipment as necessary to maintain the efficiency of the system.

(x) Pipe and equipment insulation rating. Flame spread shall not exceed 25 and smoke development rating shall not exceed 150 for pipe insulation as determined by an independent testing laboratory in accordance with National Fire Protection Association 255, Standard Method of Test of Surface Burning Characteristics of Building Materials, 2000 edition. Smoke development rating for pipe insulation located in environmental air areas shall not exceed 50.

(xi) Asbestos insulation. Asbestos insulation shall not be used.

(B) Plumbing fixtures. Plumbing fixtures shall be made of nonabsorptive acid-resistant materials and shall comply with the recommendations of the National Standard Plumbing Code and this paragraph.

(i) Sink and lavatory controls. All fixtures used by medical and nursing staff and all lavatories used by patients and food handlers shall be trimmed with valves which can be operated without the use of hands. Blade handles used for this purpose shall not be less than four inches in length. Single lever or wrist blade devices may be used.

(ii) Clinical sink traps. Clinical sinks shall have an integral trap in which the upper portion of a visible trap seal provides a water surface.

(iii) Sinks for disposal of plaster of paris. Sinks used for the disposal of plaster of paris shall have a plaster trap.

(iv) Back-flow or siphoning. All plumbing fixtures and equipment shall be designed and installed to prevent the back-flow or back-siphonage of any material into the water supply. The over-the-rim type water inlet shall be used wherever possible. Vacuum-breaking devices shall be properly installed when an over-the-rim type water inlet cannot be utilized.

(v) Drinking fountain. Each drinking fountain shall be designed so that the water issues at an angle from the vertical, the end of the water orifice is above the rim of the bowl, and a guard is located over the orifice to protect it from lip contamination.

(vi) Sterilizing equipment. All sterilizing equipment shall be designed and installed to prevent not only the contamination of the water supply but also the entrance of contaminating materials into the sterilizing units.

(vii) Hose attachment. No hose shall be affixed to any faucet if the end of the hose can become submerged in contaminated liquid unless the faucet is equipped with an approved, properly installed vacuum breaker.

(viii) Bedpan washers and sterilizers. Bedpan washers and sterilizers shall be designed and installed so that both hot and cold water inlets shall be protected against back-siphonage at maximum water level.

(ix) Flood level rim clearance. The water supply spout for lavatories and sinks required in patient care areas shall be mounted so that its discharge point is a minimum of five inches above the rim of the fixture.

(x) Scrub sink controls. Scrub sinks and lavatories used for scrubbing in procedure rooms shall be trimmed with foot, knee, or ultrasonic controls. Single lever wrist blades are not acceptable at scrub sinks.

(xi) Floor drains or floor sinks. Where floor drains or floor sinks are installed, they shall be of a type that can be easily cleaned by removal of the cover. Removable stainless steel mesh shall be provided in addition to grilled drain cover to prevent entry of large particles of waste which might cause stoppages.

(xii) Under-counter piping. Under-counter piping and above floor drains shall be arranged (raised) so as not to interfere with cleaning of floor below the equipment.

(xiii) Ice machines. All ice-making machines used for human consumption shall be of the self-dispensing type. Copper tubing shall be provided for supply connections to ice machines.

(xiv) Food disposal units. A food disposal unit shall only be permitted in the dietary department (§133.163(e) of this title).

(5) General electrical requirements. This paragraph contains common electrical requirements. The hospital shall comply with the requirements of this paragraph and with any specific electrical requirements for the particular unit of the hospital in accordance with §133.163 of this title.

(A) Electrical installations. All new electrical material and equipment, including conductors, controls, and signaling devices, shall be installed in compliance with applicable sections of the National Fire Protection Association 70, National Electrical Code, 1999 edition (NFPA 70), and NFPA 99 and as necessary to provide a complete electrical system. Electrical systems and components shall be listed by nationally recognized listing agencies as complying with available standards and shall be installed in accordance with the listings and manufacturers' instructions.

(i) All fixtures, switches, sockets, and other pieces of apparatus shall be maintained in a safe and working condition.

(ii) Extension cords and cables shall not be used for permanent wiring.

(iii) All electrical heating devices shall be equipped with a pilot light to indicate when the device is in service, unless equipped with a temperature limiting device integral with the heater.

(iv) All equipment, fixtures, and appliances shall be properly grounded in accordance with NFPA 70.

(v) Under-counter receptacles and conduits shall be arranged (raised) to not interfere with cleaning of floor below the equipment.

(B) Installation testing and certification.

(i) Installation testing. The electrical installations, including alarm, nurses calling system and communication systems, shall be tested to demonstrate that equipment installation and operation is appropriate and functional.

(ii) Grounding system testing. The grounding system shall be tested as described in NFPA 99, 4.3.3, for patient care areas in new or renovated work. The testing shall be performed by a qualified electrician or their qualified electrical testing agent. The electrical contractor shall provide a letter stating that the grounding system has been tested in accordance with NFPA 99, the testing device use complies with NFPA 99, and whether the grounding system passed the test. The letter shall be signed by the qualified electrical contractor, or their designated qualified electrical testing agent, certifying that the system has been tested and the results of the test are indicated.

(C) Electrical safeguards. Shielded isolation transformers, voltage regulators, filters, surge suppressors, and other safeguards shall be provided as required where power line disturbances are likely to affect fire alarm components, data processing, equipment used for treatment, and automated laboratory diagnostic equipment.

(D) Services and switchboards. Electrical service and switchboards serving the required hospital components shall be installed above the designated 100-year flood plain. Main switchboards shall be located in separate rooms, separated from adjacent areas with one-hour fire rated enclosures containing only electrical switchgear and distribution panels and shall be accessible to authorized persons only. These rooms shall be ventilated to provide an environment free of corrosive or explosive fumes and gases, or any flammable and combustible materials. Switchboards shall be located convenient for use and readily accessible for maintenance as required by NFPA 70, Article 384. Overload protective devices shall operate properly in ambient temperatures.

(E) Panelboards. Panelboards serving normal lighting and appliance circuits shall be located on the same floor as the circuits they serve. Panelboards serving critical branch emergency circuits shall be located on each floor that has major users (operating rooms, delivery suites, intensive care, etc.) and may also serve the floor above and the floor below. Panelboards serving life safety branch circuits may serve three floors, the floor where the panelboard is located, and the floors above and below.

(F) Wiring. All conductors for controls, equipment, lighting and power operating at 100 volts or higher shall be installed in accordance with the requirements of NFPA 70, Article 517. All surface mounted wiring operating at less than 100 volts shall be protected from mechanical injury with metal raceways to a height of seven feet above the floor. Conduits and cables shall be supported in accordance with NFPA 70, Article 300.

(G) Lighting.

(i) Lighting intensity for staff and patient needs shall comply with guidelines for health care facilities set forth in the Illuminating Engineering Society of North America (IESNA) Handbook, 2000 edition, published by the IESNA, 120 Wall Street, Floor 17, New York, New York 10005.

(I) Consideration should be given to controlling intensity and wavelength to prevent harm to the patient's eyes (i.e., retina damage to premature infants and cataracts due to ultraviolet light).

(II) Approaches to buildings and parking lots, shall be illuminated. All rooms including storerooms, electrical and mechanical equipment rooms, and all attics shall have sufficient artificial lighting so that all parts of these spaces shall be clearly visible.

(III) Consideration should be given to the special needs of the elderly. Excessive contrast in lighting levels that makes effective sight adaptation difficult shall be minimized.

(ii) Means of egress and exit sign lighting intensity shall comply with NFPA 101, §§7.8 - 7.10.

(iii) Electric lamps which may be subject to breakage or which are installed in fixtures in confined locations when near woodwork, paper, clothing, or other combustible materials, shall be protected by wire guards, or plastic shields.

(iv) Ceiling-mounted surgical and examination light fixtures shall be suspended from rigid support structures mounted above the ceiling.

(H) Receptacles. Only listed hospital grade single-grounding or duplex-grounding receptacles shall be used in all patient care areas. This does not apply to special purpose receptacles.

(i) Installations of multiple-ganged receptacles shall not be permitted in patient care areas.

(ii) Electrical outlets powered from the critical branch shall be provided in all patient care, procedure and treatment locations in accordance with NFPA 99, §4.4.2.2.2.3. At least one receptacle at each patient treatment or procedure location shall be powered from the normal power panel.

(iii) Replacement of malfunctioning receptacles and installation of new receptacles powered from the critical branch in existing facilities shall be accomplished with receptacles of the same distinct color as the existing receptacles.

(iv) In locations where mobile X-ray or other equipment requiring special electrical configuration is used, the additional receptacles shall be distinctively marked for the special use.

(v) Each receptacle shall be grounded to the reference grounding point by means of a green insulated copper equipment grounding conductor.

(vi) All critical care area receptacles shall be identified. The face plate for the receptacle(s) shall have a nonremovable label or be engraved indicating the panel and circuit number.

(I) Equipment.

(i) Equipment required for safe operation of the hospital shall be powered from the equipment system in accordance with the requirements contained in NFPA 99, §4.4.2.2.3.

(ii) Boiler accessories including feed pumps, heat-circulating pumps, condensate return pumps, fuel oil pumps, and waste heat boilers shall be connected and installed to provide both normal and standby service.

(iii) Laser equipment shall be installed according to manufacturer recommendations and shall be registered with the Radiation Branch, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756.

(J) Ground fault circuit interrupters (GFCI). GFCI receptacles shall be provided for all general use receptacles located within three feet of a wash basin or sink. When GFCI receptacles are used, they shall be connected to not affect other devices connected to the circuit in the event of a trip. Receptacles connected to the critical branch that may be used for equipment that should not be interrupted do not have to be GFCI protected. Receptacles in wet locations, as defined by NFPA 70, §517.20 and §517.21, shall be GFCI protected regardless of the branch of the electrical system serving the receptacle.

(K) Grounding requirements. In areas such as critical care units and special nurseries where a patient may be treated with an internal probe or catheter connected to the heart, the ground system shall comply with applicable sections of NFPA 99 and NFPA 70.

(L) Nurses calling systems. Three different types of nurses calling systems are required to be installed in a hospital: a nurses regular calling system; a nurses emergency calling system; and a staff emergency assistance calling system. The hospital shall comply with the requirements of this subparagraph in addition to any specific requirements for nurses calling systems for the particular unit of the hospital in accordance with §133.163 and Table 7 of §133.169(g) of this title. Where required in this subparagraph, a distinct visible signal is provided when a colored dome light lamp, or particular combination of colored lamps is used for only one type of call. Different flash rates do not meet this requirement.

(i) A nurses regular calling system is intended for routine communication between each patient and the nursing staff. Activation of the system at a patient's regular calling station will sound a repeating (every 20 seconds or less) distinct audible signal at the nurse station, indicate type and location of call on the system monitor, and activate a distinct visible signal in the corridor at the patient suites door. In multi-corridor nursing units, additional visible signals shall be installed at corridor intersections. The audible signal shall be canceled and two-way voice communication between the patient room and the nursing staff shall be established at the unit's nursing station when the call is answered by the nursing staff. The visible signal(s) in the corridor shall be canceled upon termination of the call. Calls shall activate visible signals in accordance with Table 7 of §133.169(g) of this title. An alarm shall activate at the nurses station when the call cable is unplugged.

(ii) A nurses emergency calling system shall be installed in all toilets used by patients to summon nursing staff in an emergency. Activation of the system shall sound a repeating (every 5 seconds or less) a distinct audible signal at the nurse station, indicate type and location of call on the system monitor, and activate a distinct visible signal in the corridor at the patient suites door. In multi-corridor nursing units, additional visible signals shall be installed at corridor intersections. The visible and audible signals shall be cancelable only at the patient calling station. Calls shall activate visible signals in accordance with Table 7 of §133.169(g) of this title. When conveniently located and accessible from both the bathing and toilet fixtures, one emergency call station may serve one bathroom. A nurses emergency call system shall be accessible to a collapsed patient lying on the floor. Inclusion of a pull cord extending to within six inches of the floor will satisfy this requirement.

(iii) A staff emergency assistance calling system (code blue) is intended to be used by staff to summon additional help in an emergency. In open suites, an emergency assistant call system device shall be located at the head of each bed and in each individual room. The emergency assistance calling device can be shared between two beds if conveniently located. Activation of the system will sound a distinct audible signal at the nursing unit's nurses station or at a staffed control station of a suite, department or unit, indicate type and location of call on the system monitor and activate a distinct visible signal in the corridor at the patient suites door. In multi-corridor nursing units, additional visible signals shall be installed at corridor intersections. Calls shall activate audible and visible signals in accordance with Table 7 of §133.169(g) of this title. A visible system shall clearly define the alarm location to a continuously staffed back up area (other than the nurse station or an administrative center) from which assistance can be summoned. Alternatively, back up may be provided via automatic annunciation from the staff emergency assistance calling system through wireless phones or pagers. The system shall have voice communication capability so that the type of emergency or help required may be specified between the point of alarm and the unit's nurse station.

(M) Emergency electric service. A type I essential electrical system shall be provided in each hospital in accordance with requirements of NFPA 99; NFPA 101, and National Fire Protection Association 110, Standard for Emergency and Standby Power Systems, 2002 edition.

(i) When the emergency and standby power systems require a fuel source with tank, the fuel storage capacity tank shall have enough fuel for a period of 24 hours.

(ii) When a vapor liquefied petroleum gas (LPG) systems (natural gas) system is used, the 24-hour fuel capacity on-site is not required. The vapor withdrawal LPG system shall require a dedicated fuel supply.

(iii) When the emergency generator(s) and electrical transformer(s) are located within the same area, they shall be located at least 10 feet apart.

(N) Fire alarm system. A fire alarm system which complies with NFPA 101, §18.3.4, and with NFPA 72, Chapter 6 requirements, shall be provided in each facility. The required fire alarm system components are as follows:

(i) A fire alarm control panel (FACP) shall be installed at a continuously attended (24 hour) location. A remote fire alarm annunciator listed for fire alarm service and installed at a continuously attended location and is capable of indicating both visual and audible alarm, trouble and supervisory signals in accordance with the requirements of NFPA 72 may be substituted for the FACP.

(ii) Manual fire alarm pull stations shall be installed in accordance with NFPA 101, §18.3.4.

(iii) Smoke detectors for door release service shall be installed on the ceiling at each door opening in the smoke partition in accordance with NFPA 72, §6.15.6, where the doors are held open with electromagnetic devices conforming with NFPA 101, §18.2.2.6.

(iv) Ceiling-mounted smoke detector(s) shall be installed in room containing the FACP when this room is not attended continuously by staff as required by NFPA 72, §4.4.5.

(v) Smoke detectors shall be installed in air ducts in accordance with NFPA 72, §5.14.4.2 and §5.14.5 and NFPA 90A, §6.4.2.

(vi) Smoke detectors shall be installed in return air ducts in accordance with requirements of NFPA 72 §5.14.4.2.2 and §5.14.5 and NFPA 90A, §6.4.2.2.

(vii) Fire sprinkler system water flow switches shall be installed in accordance with requirements of NFPA 101, §9.6.2; NFPA 13, §6.9; and NFPA 72, §8.5.3.3.3.4.

(viii) Sprinkler system valve supervisory switches shall be installed in accordance with the requirements of NFPA 72, §6.8.5.5.

(ix) Audible alarm indicating devices shall be installed in accordance with the requirements of NFPA 101, §18.3.4, and NFPA 72, §7.4.

(x) Visual fire alarm indicating devices which comply with the requirements of paragraph (1)(D) of this subsection and NFPA 72, §7.5, shall be provided.

(xi) Devices for transmitting alarm for alerting the local fire brigade or municipal fire department of fire or other emergency shall be provided. The devices shall be listed for the fire alarm service by a nationally recognized laboratory, and be installed in accordance with such listing and the requirements of NFPA 72.

(xii) A smoke detection system for spaces open to corridor(s) shall be provided when required by NFPA 101, §18.3.6.1.

(xiii) A fire alarm signal notification which complies with NFPA 101, §9.6.3, shall be provided to alert occupants of fire or other emergency.

(xiv) Wiring for fire alarm detection circuits and fire alarm notification circuits shall comply with requirements of NFPA 70, Article 760.

(xv) A smoke detection system for elevator recall shall be located in elevator lobbies, elevator machine rooms and at the top of elevator hoist ways as required by NFPA 72, §6.15.3.10.

(I) The elevator recall smoke detection system in new construction shall comply with requirements of American Society of Mechanical Engineers/American National Standards Institute (ASME/ANSI) A17.1, Safety Code for Elevators and Escalators, 2000 edition. The publications of the ASME/ANSI referenced in this section may be obtained by writing ASME/ANSI, United Engineering Center, 345 East 47th Street, New York, N.Y. 10017.

(II) The elevator recall smoke detection system in existing hospitals shall comply with requirements of ASME/ANSI A17.3, Safety Code for Existing Elevators and Escalators, 2002 edition.

(xvi) Smoke detectors for initiating smoke removal from windowless anesthetizing areas shall be provided in accordance with NFPA 99, §6.4.1.2.

(xvii) Smoke detectors for initiating smoke removal from surgical suites shall be provided in accordance with NFPA 99, §6.4.1.3.

(xviii) A smoke detection system for initiating smoke removal from atriums shall be located above the highest floor level of the atrium and at return intakes from the atrium in accordance with National Fire Protection Association 92B, Guide for Smoke Management Systems in Malls, Atria, and Large Areas, 2000 edition.

(xix) Smoke detector(s) for shutdown of air handling units shall be provided. The detectors shall be installed in accordance with NFPA 90A, §6.4.3.

(O) Telecommunications and information systems. Telecommunications and information systems central equipment shall be installed in a separate location designed for the intended purpose. Special air conditioning and voltage regulation shall be provided as recommended by the manufacturer.

(P) Lightning protection systems. When installed, lightning protection systems shall comply with National Fire Protection Association 780, Standard for the Installation of Lightning Protection Systems, 2000 edition.

§133.163. Spatial Requirements for New Construction.

(a) Administration and public suite.

(1) Architectural requirements. The following rooms or areas shall be provided.

(A) Primary entrance. An entrance at grade level shall be accessible and protected from inclement weather with a drive under canopy for loading and unloading passengers.

(B) Lobby. A main lobby shall be located at the primary entrance and shall include a reception and information counter or desk, waiting space(s), public toilet facilities, public telephones, drinking fountain(s), and storage room or alcove for wheelchairs.

(C) Admissions area. An admissions area shall include a waiting area, work counters or desk, private interview spaces, and storage room or alcove for wheelchairs. The waiting area and wheelchair storage may be shared with similar areas located in the main lobby. The admission area may be omitted if exclusive bedside registration is used.

(D) General or individual office(s). Office space shall be provided for business transactions, medical and financial records, and administrative and professional staffs.

(E) Multipurpose room(s). Room(s) shall be provided for conferences, meetings, and health education purposes including provisions for showing visual aids.

(F) Storage. Storage for office equipment and supplies shall be provided. The construction protection for the storage room or area shall be in accordance with the National Fire Protection Association 101, Life Safety Code, 2003 edition (NFPA 101), §18.3.2. All documents published by the NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address and telephone number: Post Office Box 9101, 1 Batterymarch Park, Quincy, Massachusetts 02269-9101, (800) 344-3555; the NFPA website address is http://catalog.nfpa.org.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title (relating to New Construction Requirements).

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(b) Cart cleaning and sanitizing unit.

(1) Architectural requirements.

(A) Cart cleaning, sanitizing and storage facilities shall be provided for carts serving central services, dietary services, and linen services.

(B) Cart facilities may be provided for each service or be centrally located.

(C) Hand washing fixtures shall be provided in cart cleaning, sanitizing and storage areas.

(2) Details and finishes. When interior cart cleaning facilities are provided, details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Flooring in the cart cleaning and sanitizing unit shall be of the seamless type, or ceramic or quarry tile as required by §133.162(d)(2)(B)(iii)(III) or (IV) of this title.

(B) Ceilings in the cart cleaning and sanitizing unit shall be the monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) Hand washing fixtures shall be provided with hot and cold water. Hot and cold water fixtures shall be provided in cart cleaning and sanitizing locations regardless of whether or not they are interior or exterior.

(B) Where floor drains or floor sinks are installed, they shall be of a type that can be easily cleaned by removal of the cover. Removable stainless steel mesh shall be provided in addition to a grilled drain cover to prevent entry of large particles of waste which might cause stoppages. Floor drains and floor sinks shall be located to avoid conditions where removal of covers for cleaning is difficult.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(c) Central sterile supply suite.

(1) Architectural requirements.

(A) General. When obstetrical or surgical services are provided, the following rooms or areas shall be provided.

(i) Decontamination room. This room shall be physically separated from all other areas of the suite. The room shall include work counters or tables, flush type utility sink, equipment for initial disinfection, and hand washing facilities with hands-free operable controls. Materials shall be transferred from the decontamination room to the clean assembly room by way of pass-through doors, windows or washer equipment. The dirty side of the decontamination room may be combined with a soiled utility room if all functions for each space are provided within the room.

(ii) Clean and assembly room. The room shall include counters or tables, equipment for sterilizing and hand washing facilities with hands-free operable controls. Clean and soiled work areas shall be physically separated.

(iii) Breakdown storage room. A storage room for breakdown of supplies shall be provided. The storage room shall have adequate areas and counters for breakdown of prepackaged supplies.

(iv) Sterile and clean supply room. A sterile and clean supply room shall be provided. Storage of sterile and clean supplies shall not occur within the breakdown room.

(v) Equipment storage. An equipment storage room shall be provided.

(vi) Cart storage room. The storage room for distribution carts shall be adjacent to clean and sterile storage and close to main distribution points.

(vii) Multipurpose room. The equipment storage and cart storage room can be combined into a multipurpose room.

(B) Service areas. The central supply suite shall provide the following.

(i) Office space. Office space for director of central services.

(ii) Staff toilets. Facilities may be outside the unit but must be convenient for staff use and shall contain hand washing fixtures with hands-free operable controls.

(iii) Locker room. When provided, the locker room for staff shall include lockers, toilets, lavatories, showers, and male and female dressing rooms or cubicles. A central changing locker room may be shared and made available within the immediate area of the central sterile supply suite.

(iv) Housekeeping room. A housekeeping room shall be provided and contain a floor receptor or service sink and storage space for housekeeping supplies and equipment. The housekeeping room shall be located on the decontamination/soiled side of the central sterile supply suite.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details. Mirrors shall not be installed at hand washing fixtures in clean and sterile supply areas.

(B) Finishes.

(i) Flooring used in the decontamination room and the clean assembly room shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Ceilings in the decontamination room, clean assembly room, and supply storage room shall be the monolithic type in accordance with §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) The sterile supply room and the clean and assembly room shall include provisions for ventilation, humidity, and temperature control.

(B) When provided, installations of ethylene oxide (EO) sterilizers shall comply with the requirements of 30 TAC §106.417 (relating to Ethylene Oxide Sterilizers), administered by the Texas Commission on Environmental Quality (TCEQ), and the following requirements.

(i) All source areas shall be exhausted, including the sterilizer equipment room, service and aeration areas, over sterilizer door, and the aerator. If the EO cylinders are not located in a well-ventilated unoccupied equipment space, an exhaust hood shall be provided over the cylinders. The relief valve shall be terminated in a well-ventilated, unoccupied equipment space, or outside the building.

(ii) General airflow shall be away from sterilizer operators and towards the sterilizers.

(iii) A dedicated exhaust fan and an exhaust duct system shall be provided for EO sterilizers. The exhaust outlet to the atmosphere shall be located on the highest roof, directed upward, and not less than 25 feet from any air intake. A legible warning sign shall be provided to identify the exhaust stack on the roof.

(iv) An audible and visual alarm located in sterilizer work area and a 24-hour staffed location shall be activated upon loss of airflow in the exhaust system.

(C) Filtration requirements for air handling units serving the central sterile supply suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title (relating to Tables).

(D) Duct linings exposed to air movement shall not be used in ducts serving the central sterile supply suite unless terminal filters of at least 90% efficiency are installed downstream of linings. This requirement shall not apply to mixing boxes and acoustical traps that have special coverings over such lining.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of

this title. When medical gas systems are provided, the systems shall comply with §133.162(d)(4) of this title and this paragraph.

(A) Drainage and waste piping shall not be installed within the ceiling or installed in an exposed location in sterile areas unless precautions are taken to protect the space below from leakage and condensation from necessary overhead piping. Any required secondary protection shall be labeled, "code required secondary drain system" every 20 feet in a highly visible print or label.

(B) No plumbing lines may be exposed or on walls where possible leaks would create a potential of contamination of the sterile areas.

(C) The compressed air required for the decontamination room shall not be connected to the medical air piping distribution system such as supporting breathable air for respiratory assistance needs, anesthesia machines, intermittent positive pressure breathing machine (IPPB), etc. A separate compressed air supply source shall be provided for maintenance and equipment needs for facility support use.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph. Electrical circuit(s) to equipment in wet areas shall be provided with ground fault circuit interrupters (GFCIs).

(d) Critical care unit.

(1) Architectural requirements.

(A) General. When a critical care unit(s) (CCU) (also known as intensive care unit) is provided, the unit(s) may be classified as general CCU, coronary CCU (CCCU) or pediatric CCU (PCCU). Requirements for neonatal intensive care units (NCCU) are stated in subsection (u) of this section.

(i) The CCU(s) shall be a separate suite(s) operated separately from other units of the hospital. The location shall be arranged to eliminate the need for through traffic.

(ii) When elevator transport is required for critically ill patients, the size of the elevator cab, mechanisms and controls shall meet the specialized needs.

(B) CCU services and facilities. The following services and facilities shall apply to all classifications of CCUs unless otherwise noted.

(i) The patient area (whether separate rooms, cubicles, or multiple-bed space) shall have a minimum clear floor area of 200 square feet per bed exclusive of anterooms, vestibules, toilet rooms, closets, lockers, wardrobes, and/or alcoves. A minimum of 13 feet width shall be provided for the head wall for each bed.

(ii) When an open ward plan is used, at least one private room for every six ward beds shall be provided for medical isolation or psychological needs.

(iii) A minimum of one airborne infection isolation room shall be provided for each type of CCU suite. The number of airborne infection isolation rooms shall be determined based on an infection control risk assessment. Each room shall comply with requirements of subsection (t)(1)(C)(iii) and (iv) of this section. In addition, the isolation room shall comply with clause (i) of this subparagraph.

(iv) When private rooms or cubicles are provided, view panels in the door or walls of these rooms are required. Curtains or other means shall be provided to cover the viewing panels when visual privacy is required.

(v) For open ward environments in adult and pediatric units, the clearance between a bed and a wall/partition shall be a minimum of five feet. The clearance between sides of beds shall be a minimum of eight feet. The minimum distance at the foot of the bed shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space requirement at the foot of the bed may be shared between two beds. The multiple-bed CCU wards shall contain cabinets, work counters, and hand washing fixtures with hands-free operable controls. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagrams A and B of §133.169(h) of this title.

(vi) Each room and ward shall be located on an exterior wall and shall have a window. In a ward, one window may serve more than one patient. The window sill height shall not exceed five feet above the floor. Patient beds shall not be located more than 50 feet from an exterior window. Patients' views to outside windows shall be direct. When partitions are used, the patient's view to the outside window(s) may be through no more than two separate clear vision panels. Windows shall be in accordance with subsection (t)(2)(A)(v) of this section.

(vii) Hand washing fixtures with hands-free operable controls shall be located in or adjacent to the nurse station, inside of each room at the entrance of the room, and at a ratio of one fixture to each three beds for an open ward layout. Hand washing fixtures shall be sized to contain splashing and conveniently distributed throughout the ward. When a combination modular swivel/fixed toilet and hand washing fixture is provided, hospital administration shall provide a letter (on hospital letterhead) indicating if the toilet is for staff convenience (bed pan washing) or for patient use.

(I) If the toilet is for patient use, an additional hand washing fixture shall be provided in each room at the entrance of the room. If the modular toilet/hand washing unit is for patient use, provision shall be made for patient privacy and odor control. The toilet room exhaust shall be in accordance with Table 3 of §133.169(c) of this title.

(II) When the modular toilet/hand washing unit is for staff use, it shall be near the entrance to the room.

(viii) The nurse station shall be located to permit direct visual observation of each patient served. Video cameras or mirrors shall not be substituted for direct visual observation. The nurse station shall have space for counters and storage. The counter height shall not exceed 42 inches. The nurse station may be combined with or include centers for reception and communication.

(ix) When individual nurse substations are provided and located at each patient room(s), they shall be located to permit direct visual observation of each patient served. The nurse substation shall have space for a counter, storage space and a recessed sitting space. The substation shall, at a minimum, be recessed one foot six inches from the egress corridor.

(x) Storage and preparation of medication may be done from a room, alcove area or from a self-contained dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks are not acceptable for hand washing.

(xi) An intravenous solution support shall be provided at each patient crib, bed or bassinet. The intravenous solution shall not be suspended directly over the patient.

(xii) Storage space shall be provided for emergency equipment in the unit.

(C) CCCU. When a CCCU is provided, the CCCU shall comply with the requirements contained in subparagraph (B) of this paragraph and the following.

(i) Each CCCU bed shall be in a separate room. Equipment for monitoring cardiac patients shall be provided by visual display both at the bed location and at the nurse station.

(ii) Each coronary patient shall have direct access to a toilet room and a hand washing fixture. Swivel type commodes may be utilized in lieu of individual toilet rooms, but provision must be made for patient privacy and odor control. The toilet room exhaust rate shall be in accordance with Table 3 of §133.169(c) of this title.

(iii) When medical, surgical, and coronary critical care services are combined in one CCU suite, at least 50% of the beds shall be located in private rooms. (Note: Medical/surgical patients may utilize open areas or private critical care rooms as needed and available but, insofar as possible, coronary patients should not be accommodated in open ward areas.)

(D) PCCU. When a PCCU is provided, the unit shall comply with the requirements contained in subparagraph (B) of this paragraph and the following.

(i) The PCCU may be an open ward, private rooms, or combination of both. When an open ward plan is used, one private room is required for each 10 beds or fraction thereof.

(ii) In a multiple-bassinet/crib (sleeping unit) room/ward the clearance between the side of the sleeping unit and a wall/partition shall be a minimum of five feet. The clearance between sides of sleeping units shall be a minimum of eight feet. The minimum distance at the foot of the bassinet shall not be less than ten feet for single load area/room or sixteen feet for double load area/room. Four feet of the passage space requirement at the foot of the bassinet may be shared between two bassinets. The fixed and moveable cabinets and shelves shall not encroach upon the bassinet/crib clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram K of §133.169(h) of this title.

(iii) A sleeping space shall be provided for parents who spend long hours with the patient. This space may be within the patient room or separate from the patient area but shall be in communication with the PCCU staff.

(iv) Hand washing fixtures with hands-free operable controls shall be provided in each room near the entrance of the room, and in open wards at a minimum ratio of one fixture to each three cribs, beds or bassinets. Hand washing fixtures shall be sized to contain splashing.

(v) A room shall be provided for private discussions and shall be located within, or convenient to, the PCCU. The multipurpose room noted in subparagraph (F)(v) of this paragraph will meet this requirement if conveniently located.

(vi) Storage space for infant formula shall be provided. This functional space may be outside the PCCU but shall be available for use at all times.

(vii) Storage cabinets or closets for toys and games shall be provided within the unit.

(viii) Storage area for cots, bed linens, and other items needed for overnight accommodation of parents shall be provided in the general location of sleeping accommodations.

(ix) An examination/treatment room with a minimum of 120 square feet of clear floor area shall be located in or near the PCCU suite. The room shall contain a hand washing fixture with hands-free operable controls, storage facilities, counter, or shelf space for writing. This requirement does not apply when all patient rooms are private rooms.

(E) Additional service spaces. The following additional service spaces shall be immediately available within each type of CCU(s). These may be shared by more than one CCU (unless otherwise noted) provided that direct access is available from each.

(i) Securable closets. Securable closets or cabinet compartments for the personal effects of nursing personnel, located in or near the nurse station, shall be provided. At a minimum, these shall be large enough for purses and billfolds. Coats may be stored in closets or cabinets on each floor or in a central staff locker area.

(ii) Charting and dictation area(s) for physicians. Space for recording, record storage and reviews shall be provided near cribs, beds or bassinets. Dictation space may be in a separate room or alcove. Suitable space shall be provided when computers are used for the clinical records.

(iii) X-ray viewing area. Each type of CCU shall be provided with an X-ray viewing area and film illuminators for handling at least four films simultaneously. When the entire CCU suite is provided with digital imaging system capabilities, a minimum of two X-ray film illuminator viewers shall be provided. The film illuminators shall be mounted within the central area of the suite.

(iv) Nourishment station. The nourishment station shall contain a sink with hands-free operable controls, work counter, refrigerator, cabinets, and not be located in the medication room or the clean workroom. Space shall be included for temporary holding of unused or soiled dietary trays.

(v) Ice machine. The ice machine shall provide ice for treatment and patient use. Ice-making equipment for treatment may be in the clean workroom or the nourishment station.

(vi) Equipment storage. In addition to above, twenty square feet of equipment storage shall be provided for each patient station. These storage areas shall be out of the way of the corridor traffic.

(vii) Stretcher storage alcove. The alcove provided for stretcher or bassinet storage shall be located out of direct line of traffic.

(viii) Clean workroom. The room shall contain a work counter, a hand washing fixture with hands-free operable controls, and storage facilities for clean and sterile supplies.

(ix) Clean linen storage. There shall be a designated area for clean linen storage. This may be within a clean workroom, a separate closet, or an approved distribution system. If a closed cart system is used, storage of the cart may be in an alcove.

(x) Soiled workroom. The soiled workroom shall contain a work counter, a clinical sink with hands-free operable controls or equivalent flushing rim type fixture with hot and cold mixing faucet, separate hand washing facilities, and separate waste and soiled linen receptacles.

(xi) Soiled holding room. When provided, soiled holding rooms used only for temporary holding of soiled material may omit the clinical sink and work counter.

(xii) Housekeeping room. A housekeeping room shall be provided within or immediately adjacent to the CCU. It shall not be shared with other nursing units or departments.

(F) Other required areas/rooms. The following areas/rooms shall be provided and may be located outside the unit if conveniently accessible.

(i) Waiting space. A visitors' waiting space shall be provided with toilet facility(ies), public telephone(s), and drinking fountain(s). One waiting space may serve other CCUs.

(ii) Offices. Room(s) shall be provided for critical care medical and nursing management and administrative personnel. The offices shall be large enough to permit consulting with members of the critical care team and visitors. The offices shall be linked with the unit by telephone or an intercommunications system.

(iii) Staff lounge. A staff lounge shall include toilet facilities with a hand washing fixture with hands-free operable controls. The lounge(s) shall be located so that staff may be recalled quickly to the patient area in emergencies. One lounge may serve multiple CCUs when the lounge is adjacent to the units. Toilet facilities may be shared as long as privacy is maintained for changing areas.

(iv) On-call rooms. Physicians and other staff on 24-hour on-call work schedules shall be provided with sleeping rooms with access to a shower(s), toilet(s), and lavatory(ies). If on-call room(s) are not within the CCU served, a dedicated telephone or intercom system shall connect the on-call room(s) to the CCU(s).

(v) Multipurpose room(s). A multipurpose room for staff, patients, and patients' families for patient conferences, reports, education, and training sessions shall be provided. This room(s) must be accessible to each nursing unit.

(vi) A consultation room shall be provided, if not provided elsewhere in the unit.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) At least one door to a CCU room shall be not less than four feet wide (41.5 inches clear width) and arranged to minimize interference with movement of beds and large equipment.

(ii) Sliding doors in CCUs shall not have floor tracks at the latch side of the sliding panel, have hardware that minimizes jamming possibilities, and be in accordance with §133.162(d)(2)(A)(vi) of this title.

(iii) Glazing in viewing panels shall be safety glass, wire glass, or clear plastic.

(iv) Noise control and sound attenuation in an open ward environment shall be a design factor and meet the requirements contained in Table 1 of §133.169(a) of this title.

(v) Recreation rooms, exercise rooms, equipment rooms, and similar spaces where impact noises may be generated shall not be located directly over CCU(s), unless special provisions are made to minimize such noise.

(B) Finishes.

(i) Flooring used in soiled workrooms shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Ceilings in the soiled workroom shall be monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph. Room recirculating units shall not be used.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) Receptacles at each bed location in a CCU(s) shall be served by two branch circuits, one or more from the critical branch panel of the emergency electrical system and one or more from the normal system. One critical branch circuit shall serve only one bed location. All branch circuits from the normal system shall be from a single panelboard. All branch circuits from the emergency electrical system shall be from a single panelboard.

(ii) A minimum of seven hospital grade duplex outlets shall be conveniently located at the head of each bed, crib or bassinet. At least three of these duplex outlets shall be on the critical branch of the emergency electrical system.

(iii) Hospital grade receptacles in the PCCU shall be tamper-resistant or provided with GFCIs.

(B) Nurses calling systems. The nurse call system shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(e) Dietary suite.

(1) Architectural requirements.

(A) General. Construction, equipment, and installation shall comply with §§229.161 - 229.171 of this title (relating to Texas Food Establishments).

(B) Food service facilities. Food services shall be provided by an on-site food preparation system or an off-site food service system or a combination of the two. The following minimum functional elements shall be provided on site regardless of the type of dietary services.

(i) Dining area. Provide dining space(s) for ambulatory patients, staff, and visitors. These spaces shall be separate from the food preparation and distribution areas.

(ii) Receiving area. This receiving area shall have direct access to the outside for incoming dietary supplies or off-site food preparation service and shall be separate from the general receiving area. The receiving area shall contain a control station and an area for breakout for loading, unloading, uncrating, and weighing supplies. The entrance area to the receiving area shall be covered from the weather.

(iii) Storage spaces. Storage spaces shall be convenient to receiving area and food preparation area and shall be located to exclude traffic through the food preparation area. Regardless of the type of food services provided, the facility shall provide storage of food for emergency use for a minimum of four calendar days.

(I) Storage space(s). Storage space(s) shall be provided for bulk, refrigerated, and frozen foods.

(II) Cleaning supply storage. This room or closet shall be used to store nonfood items that might contaminate edibles. This storage area may be combined with the housekeeping room.

(iv) Food preparation area. Counter space shall be provided for food prep work, equipment, and an area to assemble trays for distribution for patient meals.

(v) Ice-making equipment. Ice-making equipment shall be provided for both drinks and food products (self-dispensing equipment) and for general use (storage-bin type equipment).

(vi) Hand washing. Hand washing fixtures with hands-free operable controls shall be conveniently located at all food preparation areas and serving areas.

(vii) Food service carts. When a cart distribution system is provided, space shall be provided for storage, loading, distribution, receiving, and sanitizing of the food service carts. The cart traffic shall be designed to eliminate any danger of cross-circulation between outgoing food carts and incoming soiled carts, and the cleaning and sanitizing process. Cart circulation shall not be through food processing areas.

(viii) Ware washing room. A ware washing room equipped with commercial type dishwasher equipment shall be located separate from the food preparation and serving areas. Space shall be provided for receiving, scraping, sorting, and stacking soiled tableware and for transferring clean tableware to the using areas. Hand washing facilities with hands-free operable controls shall be located within the soiled dish wash area. A physical separation to prevent cross-traffic between "dirty side" and "clean side" of the dish wash areas shall be provided.

(ix) Pot washing facilities. A three compartmented sink of adequate size for intended use shall be provided convenient to the food preparation area. Supplemental heat for hot water to clean pots and pans shall be by booster heater or by steam jet.

(x) Waste storage room. A food waste storage room shall be conveniently located to the food preparation and ware washing areas but not within the food preparation area. It shall have direct access to the hospital's waste collection and disposal facilities.

(xi) Sanitizing facilities. Storage areas and sanitizing facilities for garbage or refuse cans, carts, and mobile tray conveyors shall be provided. All containers for trash storage shall have tight-fitting lids.

(xii) Housekeeping room. A housekeeping room shall be provided for the exclusive use of the dietary department. Where hot water or steam is used for general cleaning, additional space within the room shall be provided for the storage of hoses and nozzles.

(xiii) Office spaces. An office shall be provided for the use of the food service manager or the dietary service manager. In smaller facilities, a designated alcove may be located in an area that is part of the food preparation area.

(xiv) Toilets and locker spaces. A toilet room(s) with a hand washing fixture(s) with hands-free operable controls shall be provided for the exclusive use of the dietary staff. Toilet room(s) shall not open directly into the food preparation areas, but must be in close proximity to them. For larger facilities, a locker room or space for lockers shall be provided for staff belongings.

(C) Additional service areas, rooms and facilities. When an on-site food preparation system is used, in addition to the items required in subparagraph (B) of this paragraph, the following service areas, rooms and facilities shall be provided.

(i) Food preparation facilities. When food preparation systems are provided, there shall be space and equipment for preparing, cooking, and baking.

(ii) Tray assembly line. A patient tray assembly and distribution area shall be located within close proximity to the food preparation and distribution areas.

(iii) Food storage. When food is prepared on site, the storage room shall be adequate to accommodate food for a seven calendar day menu cycle.

(iv) Additional storage room(s). An additional room(s) shall be provided for the storage of cooking wares, extra trays, flatware, plastic and paper products, and portable equipment.

(v) Drying storage area. Provisions shall be made for drying and storage of pots and pans from the pot washing room.

(D) Equipment. Equipment for use in the dietary suite shall meet the following requirements.

(i) Mechanical devices shall be heavy duty, suitable for the use intended, and easily cleaned. Where equipment is movable, provide heavy duty locking casters. Equipment with fixed utility connections shall not be equipped with casters.

(ii) Floor, wall, and top panels of walk-in coolers, refrigerators, and freezers shall be insulated. Coolers and refrigerators shall be capable of maintaining a temperature down to freezing. Freezers shall be capable of maintaining a temperature of 20 degrees below 0 degrees Fahrenheit. Coolers, refrigerators, and freezers shall be thermostatically controlled to maintain desired temperature settings in increments of two degrees or less. Interior temperatures shall be indicated digitally and visible from the exterior. Controls shall include audible and visible high and low-temperature alarm. The time of alarm shall be automatically recorded.

(iii) Walk-in units may be lockable from the outside but must have a release mechanism for exit from inside at all times. The interior shall be lighted. All shelving shall be corrosion-resistant, easily cleaned, and constructed and anchored to support a loading of at least 100 pounds per linear foot.

(iv) All cooking equipment shall be equipped with automatic shutoff devices to prevent excessive heat buildup.

(E) Vending services. When vending machines are provided, a dedicated room or an alcove shall be located so that access is available at all times.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Food storage shelves shall not be less than four inches above the finished floor and the space below the bottom shelf shall be closed in and sealed tight for ease of cleaning.

(ii) Operable windows and doors not equipped with automatic closing devices shall be equipped with insect screens.

(iii) Food processing areas in the central dietary kitchen shall have ceiling heights not less than nine feet. Ceiling-mounted equipment shall be supported from rigid structures located above the finished ceiling.

(iv) Mirrors shall not be installed at hand washing fixtures in the food preparation areas.

(B) Finishes.

(i) Floors in areas used for food preparation, food assembly, soiled and clean ware cleaning shall be water-resistant and grease-proof. Floor surfaces, including tile joints, shall be resistant to food acids.

(ii) Wall bases in food preparation, food assembly, soiled and clean ware cleaning and other areas which are frequently subject to wet cleaning methods shall be made integral and coved with the floor, tightly sealed to the wall, constructed without voids that can harbor insects, retain dirt particles, and be impervious to water.

(iii) In the dietary and food preparation areas, the wall construction, finishes, and trim, including the joints between the walls and the floors, shall be free of voids, cracks, and crevices.

(iv) The ceiling in food preparation and food assembly areas shall be washable as required by §133.162(d)(2)(B)(vi)(II) of this title.

(v) The ceiling in the soiled and clean ware cleaning area shall be of the monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) Exhaust hoods handling grease-laden vapors in food preparation centers shall comply with National Fire Protection Association 96, Standard for Ventilation Control and Fire Protection of Commercial Cooking Operations, 2001 edition. All hoods over cooking ranges shall be equipped with grease filters, fire extinguishing systems, and heat-actuated fan controls. Clean out openings shall be provided every 20 feet and at any changes in direction in the horizontal exhaust duct systems serving these hoods. (Horizontal runs of ducts serving range hoods should be kept to a minimum.)

(B) When air change standards in Table 3 of §133.169(c) of this title do not provide sufficient air for proper operation of exhaust hoods (when in use), supplementary filtered make-up air shall be provided in these rooms to maintain the required airflow direction and exhaust velocity. Make-up systems for hoods shall be arranged to minimize "short circuiting" of air and to avoid reduction in air velocity at the point of contaminant capture.

(C) Air handling units serving the dietary suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) The kitchen grease traps shall be located and arranged to permit easy access without the need to enter food preparation or storage areas. Grease traps shall be of capacity required and shall be accessible from outside of the building without need to interrupt any services.

(B) Grease traps or grease interceptors shall be located outside the food preparation area and shall comply with the requirements in the National Association of Plumbing-Heating-Cooling Contractors (PHCC), National Standard Plumbing Code, 2000 edition. This publication may be obtained from the National Association of Plumbing-Heating-Cooling Contractors, 180 South Washington Street, Falls Church, VA 22046; telephone (703) 237-8100.

(C) The material used for plumbing fixtures shall be nonabsorptive and acid-resistant.

(D) Water spouts used at lavatories and sinks shall have clearances adequate to avoid contaminating utensils and containers.

(E) Hand washing fixtures used by food handlers shall be trimmed with valves that can be operated without hands. Single lever or wrist blade devices may be used. Blade handles used for this purpose shall not be less than four inches in length.

(F) Drainage and waste piping shall not be installed within the ceiling or installed in an exposed location in food preparation centers, food serving facilities and food storage areas unless precautions are taken to protect the space below from leakage and condensation from necessary overhead piping. Any required secondary protection shall be labeled, "code required secondary drain system" every 20 feet in a highly visible print or label.

(G) No plumbing lines may be exposed overhead or on walls where possible leaks would create a potential for food contamination.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) Exhaust hoods shall have an indicator light indicating that the exhaust fan is in operation.

(B) The electrical circuit(s) to equipment in wet areas shall be provided with five milliampere GFCI.

(f) Emergency suite. This subsection applies to all hospitals (general or special) included under the hospital license, including those licensed as a multiple-location hospital.

(1) Architectural requirements.

(A) Emergency treatment area.

(i) Emergency treatment room. As a minimum requirement, all hospitals shall provide at least one emergency treatment room and facilities to handle emergencies. The room(s) and facilities shall meet the following requirements.

(I) The emergency treatment room for a single patient shall have a minimum clear area of 120 square feet clear floor area exclusive of fixed and movable cabinets and shelves. The minimum clear room dimension exclusive of fixed cabinets and built-in shelves shall be 10 feet. The emergency treatment room shall contain cabinets, medication storage, work counter, examination light, and a hand washing fixture with hands-free operable controls.

(II) When a multiple-bed emergency treatment room is provided, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of four feet. The clearance between the sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed emergency treatment room shall contain cabinets, medication storage, work counter, examination light, and a hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this subclause are illustrated in Table 8, Diagram C of §133.169(h) of this title.

(III) One hand washing fixture with hands-free operable controls shall be provided for each bed/gurney location. One hand washing fixture may serve two beds/gurneys if distributed appropriately between the two.

(IV) Storage space shall be provided within the room or suite and be under staff control for general medical-surgical emergency supplies and medications. Adequate space shall be provided for emergency equipment such as emergency treatment trays, ventilator, defibrillator, splints, cardiac monitor, etc.

(V) Locked storage space shall be provided for drugs and an area for preparation of medication with a work counter, refrigerator, and hand washing fixture with hands-free operable controls.

(VI) An alcove shall be provided for stretcher and wheelchair storage. The storage shall be located out of the line of traffic.

(VII) Patient toilet room(s) shall be provided and shall be convenient to treatment rooms, examination rooms, and holding rooms, and a hand washing fixture with hands-free operable controls.

(VIII) In a special hospital, comprehensive medical rehabilitation hospital, or pediatric and adolescent hospital, the emergency treatment room and facilities may be located anywhere in the hospital.

(ii) Additional requirements for a general hospital. Except for comprehensive medical rehabilitation hospitals and pediatric and adolescent hospitals that generally provide care that is not administered for or in expectation of compensation, a general hospital shall also meet the following requirements.

(I) Emergency entry signage. An emergency sign shall be provided at the entry from the public road(s) or street(s) serving the site. The emergency sign at the entry to the site shall be illuminated and connected to the emergency essential electrical system. Additional sign(s) on-site may be required to direct patients to the emergency treatment area entrance when the emergency treatment area is not visible from the site entry. The letters on the entry sign shall be red with a contrasting background, all capitalized, at least eight inches in height, and an arrow indicating direction.

(II) Entrances. Separate ambulance and pedestrian entrances at grade level shall be well-illuminated, identified by signs, and protected from inclement weather. The ambulance entry shall have a drive under canopy for protection from inclement weather. The emergency access to permit discharge of patients from automobile and ambulances shall be paved. Parking shall be provided near and convenient to the pedestrian entrance.

(III) Control station. A registration, reception, discharge or control station shall be located to permit staff observation and control of access to treatment room(s), pedestrian and ambulance entrances, and public waiting area(s). When a dedicated triage space is provided, it shall include a counter with a hand washing fixture with hands-free operable controls.

(IV) Public waiting room. A public waiting room shall be provided.

(V) Public facilities. Toilet facilities, public telephone(s), and drinking fountain(s) shall be provided for the exclusive use of the waiting room.

(VI) Diagnostic radiographic (X-ray) room. Imaging facilities for diagnostic services shall be readily available to the emergency suite. If a separate radiographic (X-ray) room is installed within the emergency suite, it shall comply with the requirements in subsection (l)(1)(A) of this section. When the diagnostic X-ray room is exclusively used for the emergency treatment area, the dressing rooms may be omitted.

(VII) Laboratory unit. Laboratory services shall be made available to the emergency suite. If a separate laboratory workroom is installed within the emergency suite, it shall comply with the requirements in subsection (n)(1)(C)(i) of this section. All laboratory services provided on site or by contractual arrangement shall comply with §133.41(h) of this title (relating to Hospital Functions and Services).

(VIII) Medical staff work area and charting area(s). A medical staff work area and charting area(s) shall be provided. The area may be combined with the reception and control area.

(IX) Clean storage room. A clean storage room shall be provided for clean supplies, linens and medications as needed. A hand washing fixture shall be provided with hands-free operable controls.

(X) Soiled workroom. The workroom shall contain a work counter, a clinical sink or equivalent flushing type fixture, hand washing fixture with hands-free operable controls, waste receptacles, and soiled linen receptacles.

(XI) Housekeeping room. The housekeeping room shall contain a floor receptor or service sink, storage space for housekeeping supplies and equipment, and be located within the suite. When automatic film processors are used, a receptacle of adequate size with hot and cold water for cleaning the processor racks shall be provided.

(XII) Staff toilets. Toilets may be outside the suite but shall be convenient for staff use and include hand washing fixtures with hands-free operable controls. When a department has four or more treatment or examination rooms, toilet facilities shall be in the suite.

(iii) Other rooms. If a hospital provides the following rooms, the rooms shall meet these requirements.

(I) Examination room. When provided, the examination room for a single patient shall have a minimum clear area of 100 square feet clear floor area exclusive of fixed and movable cabinets and shelves. The minimum clear room dimension exclusive of fixed cabinets and built-in shelves shall be 9 feet. The examination room shall contain cabinets, medication storage, work counter, examination light, and a hand washing fixture with hands-free operable controls.

(II) Multi-bed examination room. In a multiple-bed examination room the clearance between the side of the bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of the beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed examination room shall contain cabinets, work counters, and a hand washing fixture with hands-free operable controls. One hand washing fixture shall be provided for every four beds/gurneys or fraction thereof. Fixtures shall be uniformly distributed. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area.

(III) Isolation room. The need for an airborne infection isolation room in the emergency suite shall be determined by the hospital and the infection risk assessment. When the hospital provides treatment rooms to perform procedures on persons who are known or suspected of having an airborne infectious disease, these procedures shall be performed in a designated treatment room meeting airborne infection isolation ventilation requirements. The isolation room shall have functional space in accordance with clause (i)(I) of this subparagraph, and meet the ventilation requirements contained in Table 3 of §133.169(c) of this title.

(IV) Secured holding room. When provided, this room shall be constructed to allow for security, patient and staff safety,

patient observation, and sound mitigation. The secure holding room shall have a minimum clear area of 100 square feet clear floor area exclusive of fixed cabinets. The minimum clear room dimension exclusive of fixed cabinets shall be 10 feet.

(V) Orthopedic and cast room. The room(s) may be in separate room(s) or in the trauma room. The room(s) shall contain a work counter, storage for splints and orthopedic supplies, traction hooks, medication storage, examination light, and a hand washing fixture with hands-free operable controls. When a cast room is provided it shall be equipped with hand washing facilities, plaster sink, storage, and other provisions required for cast procedures.

(VI) Film processing room. When a radiographic (X-ray) room is provided, a darkroom for processing film shall be provided unless the processing equipment does not require a darkroom for loading and transfer. When daylight processing is used, the darkroom may be minimal for emergency and special uses. Film processing shall be located convenient to the darkroom.

(VII) Decontamination room. A decontamination room shall have an exterior entry point and as far as practical from any other entry point to the emergency treatment area. The internal door from the decontamination room shall open directly to the corridor into the emergency treatment area. The door shall swing into the room and be lockable against ingress from the corridor. The room shall be a minimum of 80 square feet of clear floor area with a hand washing fixture with hands-free operable controls.

(B) Holding or observation room/area.

(i) When a holding or observation room/area is provided within or adjacent to the emergency suite, it shall comply with the following.

(I) A single holding/observation room shall have a minimum clear area of 100 square feet exclusive of fixed and movable cabinets and shelves. The holding/observation room shall contain a work counter and hand washing fixture with hands-free operable controls.

(II) The single holding/observation room shall be near the nurses station and near a patient toilet room which contains a hand washing fixture with hands-free operable controls.

(III) In a multiple-bed holding/observation room/area, the clearance between the side of the bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of the beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed holding/observation room/area shall contain cabinets, work counters, and a hand washing fixture with hands-free operable controls. One hand washing fixture shall be provided for every four holding/observation beds or fraction thereof. Fixtures shall be uniformly distributed. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this subclause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(IV) In a multiple-bed holding/observation room/area, a patient toilet room with a hand washing fixture with hands-free operable controls shall be provided within the room or area.

(ii) When a multiple-bed gurney holding or observation room is not within or adjacent to the emergency suite, the following additional spaces shall be provided:

(I) stretcher and wheelchair storage alcove. The alcove provided for stretcher and wheelchair storage shall be located out of the line of traffic;

(II) clean storage room. A clean storage room shall be provided within or adjacent to the holding or observation room. The clean storage room shall be provided for clean supplies, linen and medication as needed. A hand washing fixture shall be provided with hands-free operable controls;

(III) soiled workroom. A soiled workroom shall be provided within or adjacent to the holding or observation room. The workroom shall contain a work counter, a clinical sink or equivalent flushing type fixture, hand washing fixture with hands-free operable controls, waste receptacles, and soiled linen receptacles; and

(IV) housekeeping room. A housekeeping room shall be provided within or near the holding or observation room. The housekeeping room shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment.

(C) Trauma center. When provided, a trauma center shall comply with subparagraph (B) of this paragraph and in addition contain the following.

(i) Trauma room. A minimum of one trauma room shall be provided with 250 square feet of clear floor area exclusive of aisles and fixed and moveable cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 12 feet. The trauma room shall contain a work counter, cabinets, medication storage, and examination light.

(ii) Multiple-station trauma room. When multiple-patient stations are provided, the clearance between the head of the bed/gurney to the wall/partition shall be a minimum of three feet. The clearance between the side of a bed/gurney and a wall/partition shall be a minimum of six feet. The clearance between the sides of beds/gurneys shall be a minimum of twelve feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed trauma room shall contain cabinets, medication storage, work counter, examination light, and scrub sink with hands-free operable controls. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagrams E of §133.169(h) of this title. Provisions shall be made for visual privacy between multiple stations.

(iii) Scrub facilities. A scrub station shall be located at the entrance to each trauma room either inside or outside of the room. One scrub station may serve two trauma beds/gurneys. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts. The scrub sinks shall be recessed out of the main line of traffic.

(iv) Doorways. All doorways openings from the ambulance entrance to the trauma room shall be a minimum of five feet wide.

(D) Emergency clinic. When an emergency clinic (which may also be referred to as "urgent care", "fast track", "express care", "minor care", etc.) is provided, the clinic shall be separate and distinct from the emergency treatment area and trauma center and shall meet all the requirements of subparagraph (A) of this paragraph. All facilities required by subparagraph (A) of this paragraph may be shared with the emergency treatment area and trauma center except for the emergency treatment room. The emergency treatment room(s) in the emergency clinic shall not be less than 100 square feet. The

emergency exam room(s) in the emergency clinic shall not be less than 80 square feet.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Trauma rooms shall have ceiling heights not less than nine feet.

(ii) The decontamination room shall be equipped with two hand-held showerheads with temperature controls and a dedicated holding tank with a floor drain.

(B) Finishes.

(i) Flooring used in a trauma room, treatment room, examination room, holding area, and soiled workroom shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title. Seamless type flooring is not required in the examination room in the emergency clinic.

(ii) Ceilings in soiled workrooms, isolation rooms, and trauma rooms shall be of the monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(iii) The decontamination room floor shall be self-coved to a height of six inches. The room shall have all smooth, nonporous, scrubable, nonabsorbent and nonperforated surfaces.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) Duct linings exposed to air movement shall not be used in ducts serving any trauma rooms, treatment rooms, examination rooms, holding areas, and clean room. This requirement shall not apply to mixing boxes and acoustical traps that have special coverings over such lining.

(B) When a trauma room is provided under paragraph (1)(C)(i) of this subsection, the air supply for the trauma/surgical room shall be from ceiling outlets that are as near the work centers as possible, and a minimum of two low return inlets shall be located diagonally opposite from one another.

(C) Return air inlets shall be not lower than four inches nor higher than 12 inches from floor level.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) Medical gas systems. Medical gas systems shall be provided in accordance with §133.162(d)(4)(A)(iii) of this title.

(B) Ice machine. An ice machine shall be provided for therapeutic purposes and shall be located in the clean utility room. A self-dispensing ice machine shall be provided for ice for human consumption.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) Each treatment and examination room in the emergency treatment area and trauma center shall have a minimum of six duplex electrical receptacles located convenient to the head of each bed.

(ii) Each treatment and examination room in the emergency clinic suite shall have a minimum of four duplex electrical receptacles located convenient to the head of each bed/table.

(iii) Each work counter and table shall have access to at least one duplex receptacle connected to the critical branch of the emergency electrical system.

(iv) The hospital shall provide X-ray film illuminators for handling at least four films simultaneously in all treatment, examination, and trauma rooms in the emergency treatment area. When the entire emergency treatment area is provided with digital imaging, a minimum of two X-ray film illuminators shall be provided within a central location within the emergency treatment area.

(B) Nurses calling systems. The nurse call system shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(g) Employees suite.

(1) Architectural requirements.

(A) Architectural requirements shall be in accordance with §133.162(d)(1) of this title and this paragraph.

(B) Lockers, lounges, toilets and showers shall be provided within the hospital for employees and volunteers. These facilities are in addition to, and separate from, those required for the medical staff and the public.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(h) Engineering suite and equipment areas.

(1) Architectural requirements. Architectural requirements shall be in accordance with §133.162(d)(1) of this title and this paragraph.

(A) General. The following facilities shall be provided:

(i) an engineer's office with file space and provisions for protected storage of facility drawings, records, manuals, etc.;

(ii) a general maintenance shop(s) for repair and maintenance;

(iii) a separate room(s) for building maintenance supplies and equipment. Storage of bulk solvents and flammable liquids shall be in a separate building and not within the hospital building;

(iv) a medical equipment room which includes provisions for the storage, repair, and testing of electronic and other medical equipment;

(v) a separate room or building for yard maintenance equipment and supplies. When a separate room is within the physical plant the room shall be located so that equipment may be moved directly to the exterior. Yard equipment or vehicles using flammable liquid fuels shall not be stored or housed within the general hospital building; and

(vi) sufficient space in all mechanical and electrical equipment rooms for proper maintenance of equipment. Provisions shall also be made for removal and replacement of equipment.

(B) Additional areas or room(s). Additional areas or room(s) for mechanical, and electrical equipment shall be provided within the physical plant or installed in separate buildings or weatherproof enclosures with the following exceptions.

(i) An area shall be provided for cooling towers and heat rejection equipment when such equipment is used.

(ii) An area for the medical gas park and equipment shall be provided. For smaller medical gas systems, the equipment may be housed in a room within the physical plant in accordance with National Fire Protection Association 99, Standard for Health Care Facilities, 2002 edition (NFPA 99), Chapters 4 and 8.

(iii) When provided, compactors, dumpsters, and incinerators shall be located in an area remote from public entrances.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(i) General stores.

(1) Architectural requirements. Architectural requirements shall be in accordance with §133.162(d)(1) of this title and this paragraph.

(A) General. In addition to storage facilities in individual departments, a central storage room shall be provided. General stores may be located in a separate building on-site with provisions for protection against inclement weather during transfer of supplies.

(B) Receiving. Facilities for central storage areas shall be provided with an off-street unloading and receiving area protected from inclement weather.

(C) General storage room. General storage room with a total area of not less than 20 square feet per inpatient bed shall be provided. The storage room may be within the facility, or separate building on-site. Fifty percent of the storage may be provided off-premises. When additional inpatient beds are constructed, additional general storage shall be provided.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(j) Hospital-based skilled nursing units.

(1) Architectural requirements. When a hospital-based skilled nursing unit is provided, each unit shall comply with the requirements contained in subsection (t)(1) of this section and the requirements listed below. The skilled nursing unit may be separated from the rest of the hospital with two-hour fire protection rated construction in order to define areas for certification inspections.

(A) At least 50% of patient rooms and bathrooms and all public and common use areas in a newly constructed, or reconstructed hospital-based skilled nursing unit, are required to be handicapped accessible in accordance with §133.162(d)(1)(D) of this title.

(B) At least 10% of patient rooms and bathrooms and all public and common use areas shall be made handicapped accessible in accordance with §133.162(d)(1)(D) of this title when remodeling a hospital-based skilled nursing unit or remodeling an existing nursing unit to a hospital-based skilled nursing unit.

(C) Activity and dining space shall be part of the unit. It may be located in a separate room or open to the corridor and shall be convenient to the unit. The floor area of this space shall provide at least 30 square feet per patient bed with a minimum of 160 square feet. Additional space shall be required if this space is also used for other programs.

(D) When physical and occupational therapy services are provided for rehabilitating patients, spaces and equipment that conform to program intent shall be provided. These spaces may be located in the unit or elsewhere in the hospital.

(E) Each unit shall have at least one assisted bathing wheelchair shower or tub room per floor or nursing unit. The bathtub shall be accessible to patients in wheelchairs or the shower shall accommodate a gurney. The room shall be centrally located, convenient to the units and shall be directly accessible from the corridor. The room shall have space for drying and dressing and provided with hand washing fixture with hands-free operable controls and toilet training facilities with three feet of clear space on sides and front of the water closet.

(F) A housekeeping room shall be provided for the exclusive use of the unit. The housekeeping room shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment.

(2) Details and finishes. Each unit shall comply with the requirements contained in subsection (t)(2) of this section and this paragraph.

(A) All portions of corridor walls in the unit with an uninterrupted length of two feet or more shall have graspable handrails. The handrails shall comply with NFPA 101, §7.2.2.4, and the provisions found in 16 TAC Chapter 68, Texas Accessibility Standards, April 1, 1994 edition, issued by the Texas Department of Licensing and Regulation, under the Texas Architectural Barriers Act, Texas Government Code, Chapter 469. No handrail shall protrude more than three and one-half inches into the egress corridor. All handrail ends shall be returned to the wall.

(B) Floor finishes shall comply with the requirements of §133.162(d)(2)(B)(iii) of this title.

(3) Mechanical requirements. Mechanical requirements in each unit shall be in accordance with subsection (t)(3) of this section.

(4) Plumbing fixtures and piping systems. The plumbing fixtures and piping systems shall be in accordance with subsection (t)(4) of this section.

(5) Electrical Requirements. Electrical requirements shall be in accordance with subsection (t)(5) of this section. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(k) Hyperbaric suite.

(1) Architectural requirements. When a hyperbaric suite is provided, it shall meet the requirements of Chapter 20, NFPA 99, and Chapter 18, NFPA 101.

(A) Hyperbaric chamber clearances. Multiple occupancy chambers (Class A) shall be in accordance with NFPA 99, Chapter 20. The minimum clearances for individual (Class B) hyperbaric chambers and the side of a chamber and a wall/partition shall be a minimum of three feet. The clearance between sides of chambers shall be a minimum of six feet. The minimum distance at the chamber entry shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the chamber entry may be shared between two chambers. The chamber room shall contain cabinets, medication storage, work counter and a hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the chamber clear floor space/area. The requirements of this subparagraph are illustrated in Table 8, Diagram F of §133.169(h) of this title.

(B) Service areas. The following minimum service areas and facilities shall be provided convenient to the hyperbaric chamber suite.

(i) Patient waiting area. The area shall be out of traffic, under staff control, and shall have seating capacity in accordance with the functional program. Outpatients and inpatients shall be provided with separate waiting areas with screening for visual privacy between the waiting areas. Patient waiting areas may be omitted for two or less individual hyperbaric chamber units.

(ii) Control desk and reception area. A control desk and reception area shall be provided.

(iii) Holding area. A holding area under staff control shall accommodate inpatients on stretchers or beds. Stretcher patients shall be out of the direct line of normal traffic. The patient holding area may be omitted for two or less individual hyperbaric chamber units.

(iv) Patient toilet rooms. Toilet rooms shall be provided with hand washing fixtures with hands-free operable controls and with direct access from the hyperbaric suite.

(v) Patient dressing room(s). A dressing room(s) for outpatients shall be provided and shall include a seat or bench, mirror, and provisions for hanging patients' clothing and for securing valuables. At least one dressing room shall be provided to accommodate wheelchair patients.

(vi) Staff facilities. Toilets with hand washing fixtures with hands-free operable controls may be outside the suite but shall be convenient for staff use. These facilities may be shared with an adjacent suite.

(vii) Consultation room. An appropriate consultation room for individual consultation with referring clinicians shall be provided for outpatients. This room may be shared with an adjacent suite.

(viii) Storage space. A clean storage space shall be provided for clean supplies and linens. The space shall contain a hand washing fixture with hands-free operable controls. The storage room may be shared with another department if convenient to both.

(ix) Soiled holding room. A soiled holding room shall be provided with waste receptacles and soiled linen receptacles. This room may be shared with an adjacent suite.

(x) Hand washing. A lavatory equipped for hand washing with hands-free operable controls shall be located in the room where the hyperbaric chambers are located.

(xi) Housekeeping room. The housekeeping room shall contain a floor receptor or service sink, storage space for housekeeping supplies and equipment, and be located nearby.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) Grounding of hyperbaric chambers shall be connected only to the equipment ground in accordance with NFPA 99, §3-3.2.1.2, and National Fire Protection Association 70, National Electrical Code, 1999 edition, (NFPA 70), Article 250 (A) - (C), and Article 517.

(B) Additional grounds such as earth or driven grounds shall not be permitted.

(C) The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(l) Imaging suite.

(1) Architectural requirements.

(A) General. Each hospital shall have a diagnostic radiographic (X-ray) room convenient to emergency, surgery, cystoscopy, and outpatient suites.

(i) All diagnostic imaging room sizes shall be in compliance with the manufacturer's recommendations for the specific equipment. Clearance and unobstructed space shall not be less than three feet around the diagnostic equipment.

(ii) When radiation protection is required for any diagnostic imaging room, a medical physicist licensed under the Texas Medical Physics Practice Act, Occupations Code, Chapter 602, shall specify the type, location, and amount of radiation protection to be installed for the layout and equipment selections.

(iii) Each room where radiation protection is required shall include a shielded control alcove. The control alcove shall be provided with a view window designed to permit full view of the examination table and the patient at all times.

(iv) Warning signs capable of indicating that the equipment is in use shall be provided.

(v) Diagnostic and procedure room intended for patients with airborne infectious diseases shall meet the ventilation requirements as contained in Table 3 of §133.169(c) of this title.

(B) Diagnostic X-ray and radiographic and fluoroscopy (R&F) rooms. X-ray and R&F rooms shall be in compliance with the manufacturer's recommendations for the specific equipment. Clearance and unobstructed space shall not be less than three feet around the diagnostic equipment.

(i) A control alcove shall be provided with a view window designed to provide full view of the patient at all times.

(ii) A toilet room shall be provided including a hand washing fixture with hands-free operable controls and have direct access to each R&F room and a corridor.

(C) Noninvasive angiography imaging room. When noninvasive angiography imaging is provided, the room shall have minimum clear floor area of 250 square feet exclusive of built-in shelves or cabinets. Clearance and unobstructed space shall not be less than three feet around the diagnostic equipment.

(i) A control alcove shall be provided with a view window designed to provide full view of the patient at all times.

(ii) A viewing room or area shall be provided and shall be a minimum of 10 feet in length. The viewing room or area may be provided in combination with the control room.

(iii) A scrub sink shall be near the entrance to each angiographic room and shall be recessed out of the main traffic areas or corridor. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts.

(iv) Storage space for portable equipment and supplies shall be provided.

(D) Computerized tomography (CT) scanning. When CT services are provided, the CT room(s) size shall be in compliance with the manufacturer's recommendations and shall contain the following.

(i) A control room shall be provided with a view window permitting view of the patient. The control room shall be located to allow convenient film processing.

(ii) A patient toilet shall be provided conveniently to the procedure room. When directly accessible to the scan room, the toilet shall be arranged so that a patient may leave the toilet room without having to reenter the scan room. The toilet room shall have a hand washing fixture with hands-free operable controls.

(E) Mammography. When mammography services are provided, the room(s) shall have a minimum clear floor area of 100 square feet exclusive of built-in shelves or cabinets.

(i) A control alcove shall be provided with a view window designed to provide full view of the patient at all times.

(ii) When mammography machines with built-in shielding for the operator are provided, the alcove may be omitted when approved by a medical physicist licensed under the Texas Medical Physics Practice Act, Occupations Code, Chapter 602.

(F) Magnetic resonance imaging (MRI). When MRI services are provided, the room shall be of sufficient size to house equipment but no less than 325 square feet of clear floor area exclusive of built-in shelves or cabinets.

(i) A control alcove shall be provided with a view window designed to provide full view of the patient at all times.

(ii) A separate computer room shall be provided to accommodate the equipment.

(iii) When cryogen is provided, a storage room or closet shall have a minimum clear floor area of 50 square feet for two large dewars of cryogen. A storage room or closet shall be required in areas where service to replenish supplies is not readily available.

(iv) When a darkroom is provided, the room shall be located near the required control room and shall be outside the 10-gauss field.

(v) When spectroscopy is provided, caution should be exercised in locating it in relation to the magnetic fringe fields.

(vi) Magnetic shielding may be required to restrict the magnetic field plot. Radio frequency shielding is required to attenuate stray radio frequencies.

(vii) A patient holding area shall be provided and shall be located near the MRI unit and be large enough to accommodate stretchers.

(viii) A hand washing fixture with hands-free controls shall be provided near the entrance to the MRI room and shall be recessed out of the main traffic areas or corridor.

(ix) A 3T or larger magnetic strength MRI shall be secured behind locked doors. The patient and staff entrance to the MRI shall have a traffic pattern from the waiting, dressing, holding and work areas through a lockable control station before entering the MRI. At no time shall patients or nonpatients be allowed to enter this restricted area without MRI staff present when the magnet is active.

(G) Ultrasound room. When ultrasound services are provided, the room(s) size shall be in compliance with the manufacturer's recommendations. A patient toilet room shall be provided convenient to the procedure room and a corridor. The toilet room shall have a hand washing fixture with hands-free operable controls.

(H) Cardiac catheterization laboratory. The cardiac catheterization laboratory is normally a separate suite, but may be within the imaging suite. If provided, a cardiac catheterization laboratory shall comply with the requirements of subsection (dd)(1)(C) of this section.

(I) Service areas. The following common service areas shall be provided.

(i) Patient waiting area. The area shall be out of traffic and under direct staff visual control. When the waiting area serves both outpatient and inpatients, separate areas shall be provided and include visual privacy between the waiting areas.

(ii) Control desk and reception area. A control desk and reception area shall be provided.

(iii) Holding area. The holding area shall be out of direct traffic patterns and under visual control by staff. A minimum of one stretcher station shall be provided for each three diagnostic and procedure rooms or fraction thereof. The minimum clear floor space in the holding area shall be 80 square feet exclusive of aisles and fixed and moveable cabinets and shelves. The area shall contain cabinets, a work counter, and a hand washing fixture with hands-free operable controls. The holding area may be reduced to 50 square feet exclusive of aisles and fixed and moveable cabinets and shelves for mammography, bone density and other similar procedures.

(iv) Post-procedure observation room. When invasive diagnostic X-ray services for outpatients are provided with anesthesia, a room for extended post-procedure observation of patients shall be provided. The minimum clear floor space for the observation space shall be 100 square feet exclusive of aisles and fixed and moveable cabinets and shelves. The room shall contain cabinets, a work counter, and a hand washing fixture with hands-free operable controls.

(v) Patient toilet rooms. Toilet room(s) with hand washing facilities shall be located convenient to the waiting area.

(vi) Patient dressing rooms or cubicles. Dressing rooms or cubicles shall be convenient to the waiting areas and X-ray rooms. Each room shall include a seat or bench, mirror, and provisions for hanging patients' clothing and for securing valuables. At least one dressing room shall be provided to accommodate wheelchair patients.

(vii) Hand washing facilities. A hand washing fixture with hands-free controls shall be provided in or near the entrance to each diagnostic and procedure room unless noted otherwise. When a hand washing fixture is provided in the room, the fixture shall be located near the entrance to the room or near the staff entrance. When a hand washing fixture is located outside the room, the fixture shall be recessed in the egress corridor and located within five feet of the entrance to the room. Hand washing facilities shall be arranged to minimize any incidental splatter on nearby personnel or equipment.

(viii) Staff facilities. Toilets may be outside the suite and may be shared with other departments but shall be convenient for staff use. When four or more diagnostic or procedure imaging rooms are provided, a staff toilet is required with a hand washing fixture with hands-free controls.

(ix) X-ray film illuminator viewers. When all the diagnostic and imaging procedures are provided with digital imaging, two mounted X-ray film illuminator viewers shall be provided in the central viewing area/room.

(x) Contrast media preparation. This room shall include a work counter, a sink with hands-free operable controls, and storage. One preparation room may serve any number of rooms. When prepared media is used, this area may be omitted, but storage shall be provided for the media.

(xi) Film processing room. A darkroom shall be provided for processing film unless the processing equipment normally used does not require a darkroom for loading and transfer. When daylight processing is used, the darkroom may be minimal for emergency and special uses. Film processing shall be located convenient to the procedure rooms and to the quality control area.

(xii) Quality control area or room. An area or room for film viewing shall be located near the film processor. All view boxes shall be illuminated to provide light of the same color value and intensity.

(xiii) Film storage (active). When X-ray film is used, it shall be stored in a room with a cabinet or shelves for filing patient film for immediate retrieval.

(xiv) Film storage (inactive). When X-ray film is used, a room for inactive film storage shall be provided. It may be outside the imaging suite, but must be under the administrative control of imaging suite personnel and be properly secured to protect films against loss or damage.

(xv) Storage for unexposed film. When X-ray film is used, storage facilities for unexposed film shall include protection of film against exposure or damage.

(xvi) Storage of cellulose nitre film. When used, cellulose nitrate film shall be stored in accordance with the requirements of National Fire Protection Association 40, Standard for the Storage and Handling of Cellulose Nitrate Motion Picture Film, 1994 edition.

(xvii) Additional spaces. When four or more diagnostic or procedure rooms are provided in the hospital, the following shall be required:

(I) office(s) for radiologist(s) and assistant(s);

(II) clerical office spaces, as necessary for the functional program;

(III) consultation area/room;

(IV) medication station. Storage and preparation of medication shall be done from a room, alcove area, or from a self-contained dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks are not acceptable for hand washing;

(V) clean storage room. Clean storage room shall be provided for clean supplies and linens. A hand washing fixture shall be provided with hands-free operable controls. When conveniently located, the clean storage room may be shared with another department; and

(VI) soiled workroom. The soiled workroom shall not have direct connection to the diagnostic and procedure rooms. The room shall contain a clinical sink or equivalent flushing type fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and soiled linen receptacle. When contaminated soiled material or fluid waste is not handled, only a soiled holding room shall be required.

(xviii) Housekeeping room. The room may serve multiple departments when conveniently located.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Radiation protection shall be designed, tested and approved by a medical physicist licensed under the Texas Medical Physics Practice Act, Occupations Code, Chapter 602.

(I) Room shielding calculations for linear accelerators, teletherapy units and remote control brachytherapy units must be submitted to the Department of State Health Services' Radiation Control (RC) for approval prior to use. Shielding in diagnostic radiographic rooms will be reviewed by RC inspectors, in the field, subsequent to use. Any changes in design or shielding which affects radiation exposure levels adjacent to those rooms, requires prior approval by RC. The RC mailing address is: Radiation Control, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756.

(II) Facility design and environmental controls associated with licensable quantities of radioactive material in laboratories and/or imaging rooms shall be approved by RC prior to licensed authorizations.

(ii) Where protected alcoves with view windows are required, provide a minimum of one foot six inches from the edge where the glazing and the frame connect and the outside partition edge.

(iii) Imaging procedure rooms shall have ceiling heights not less than nine feet. Ceilings containing ceiling-mounted equipment shall be of sufficient height to accommodate the equipment of fixtures and their normal movement.

(B) Finishes.

(i) Flooring used in contrast media preparation and soiled workroom shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) A lay-in type ceiling is acceptable for the diagnostic and procedure rooms.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) The cryogen gas venting from the MRI unit shall be exhausted to the exterior. When a cryogen storage room is provided to

replenish supplies, the storage room shall be vented and exhausted to the exterior.

(B) Self-contained air conditioning to supplement the cooling capacity in computer rooms is permitted.

(C) Air handling units serving the imaging suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph. When automatic film processors are used, a receptacle of adequate size with hot and cold water for cleaning the processor racks shall be provided.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) Each imaging procedure room shall have at least four duplex electrical receptacles.

(ii) A special grounding system in areas such as imaging procedures rooms where a patient may be treated with an internal probe or catheter shall comply with Chapter 9 of NFPA 99, and Article 517 of NFPA 70.

(iii) General lighting with at least one light fixture powered from a normal circuit shall be provided in imaging procedures rooms in addition to special lighting units at the procedure or diagnostic tables.

(B) Nurses calling system. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(m) Intermediate care suite (Step down suite).

(1) Architectural requirements.

(A) General. The requirements in this subsection apply to intermediate care units for acute care patients who require frequent monitoring that exceed the level of care for nursing units and less than that provided in critical care units. The suite may share services with an adjacent suite.

(B) Intermediate care services and facilities. The following services and facilities shall apply to all classifications of intermediate care unless otherwise noted.

(i) In a single-bed patient room, the minimum clear floor area shall be 150 square feet exclusive of anterooms, vestibules, toilet rooms, closets, lockers, wardrobes, and/or alcoves. A minimum of 12 feet width shall be provided for the head wall for each bed. A hand washing fixture with hands-free operable controls shall be located in the patient room and in the patient bathroom.

(ii) In a multi-bed intermediate care patient room the maximum capacity shall be no more than four patients per room. In a multiple-bed open ward patient room, the clearance between the side of a bed and a wall/partition shall be a minimum of four feet. The clearance between sides of beds shall be a minimum of eight feet. The minimum distance at the foot of the bed shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds. The ward shall contain cabinets, work counter, and washing fixture with hands-free operable controls located centrally to the beds. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram P of §133.169(h) of this title.

(iii) Each single-bed or multi-bed open ward patient room shall have access to a bathroom without having to enter the general corridor area. Each bathroom shall contain a toilet, a hand washing fixture with hands-free operable controls, bathing facilities, and a storage shelf or cabinet.

(iv) Each single and open ward patient room shall be located on an exterior wall and shall have a window. In a ward, one window may serve more than one patient. The window sill height shall not exceed three feet above the floor. Patient beds shall not be located more than 50 feet from an exterior window. Patients' views to outside windows shall be direct and not through other clear vision panels. Windows shall be in accordance with subsection (t)(2)(A)(iv) and (v) of this section.

(v) The nurse station shall be located to permit direct visual observation of each patient served. Video cameras or mirrors shall not be substituted for direct visual observation. The nurse station shall have space for counters and storage. The counter height shall not exceed 42 inches. The nurse station may be combined with or include centers for reception and communication. In multi-bed intermediate care patient room the nurse station shall be located within the room and have space for counters and storage.

(vi) When individual nurse substations are provided and located at each patient room(s), they shall be located to permit direct visual observation of each patient served. The nurse substation shall have space for counter, storage space and a recessed sitting space. The substation shall be at a minimum recessed from the egress corridor one foot six inches.

(vii) Visual privacy shall be provided each patient in multi-bed rooms. Design for privacy shall not restrict independent patient access to the corridor, lavatory, or bathroom.

(viii) Each patient shall have a separate wardrobe, locker, or closet that is suitable for hanging full-length garments and for storing personal effects. A minimum of 12 lineal inches of hanging space shall be provided per patient.

(C) Service areas. Service areas shall be located in, adjacent to, or readily available to, each nursing unit. Each service area may be arranged and located to serve more than one nursing unit. The following service areas shall be provided.

(i) A visitors' waiting space shall be provided with a toilet facility(ies), public telephone(s), and drinking fountain(s). One waiting space may serve other units on the floor.

(ii) A nurses station with a hand washing fixture with hands-free operable controls and an adjacent but separate dictation space shall be provided when the single-bed intermediate care patient rooms concept is used. An adjacent nurse station may be used and shared when feasible.

(iii) Storage space shall be provided for emergency equipment in the suite.

(iv) Storage and distribution of medication may be done from a medicine preparation room, medicine alcove area or from a self-contained medicine dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not acceptable for hand washing. The medication station may be located with the clean work room.

(v) A soiled workroom shall be provided. The room shall contain a clinical sink or equivalent flushing rim type fixture with hot and cold mixing faucet, separate hand washing facilities

with hands-free operable controls, and separate waste and soiled linen receptacles. When facilities for cleaning bedpans are provided elsewhere, the flushing rim clinical sink may be omitted.

(vi) A clean workroom or clean supply room shall be provided. A clean workroom when used for preparing patient care items shall contain a work counter, hand washing facilities with hands-free operable controls, and storage facilities for clean and sterile supplies. When used only for storage and holding as part of a distribution system of clean and sterile supplies, the work counter and hand washing facilities may be omitted.

(vii) A nourishment station containing a work counter with sink, microwave, refrigerator and storage cabinets and not located in the clean workroom shall be provided.

(viii) A conveniently located examination room shall be provided and have a minimum clear floor area of 100 square feet and contain a counter for writing and hand washing facilities with hands-free operable controls. This room may be omitted if all patient rooms on the floor are single-bed patient rooms.

(ix) A housekeeping room shall be provided and contain a service sink, and storage for housekeeping supplies and equipment. A shared nursing unit housekeeping room that is adjacent to the intermediate care suite is acceptable.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) At least one door to an intermediate care multi-bed open ward patient room shall be not less than four feet wide and arranged to minimize interference with movement of beds and large equipment.

(ii) Sliding doors in intermediate care rooms shall not have floor tracks and shall have hardware that minimizes jamming possibilities and break-away feature from any position and be in accordance with §133.162(d)(2)(A)(vi) of this title.

(B) Finishes.

(i) Flooring used in soiled workrooms shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Ceilings in the soiled workroom shall be monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph. Room recirculating units shall not be used.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) Receptacles at each bed location shall be served by two branch circuits, one or more from the critical branch panel of the emergency electrical system and one or more from the normal system. One critical branch circuit shall serve only one bed location. All branch circuits from the normal system shall be from a single panelboard. All branch circuits from the emergency electrical system shall be from a single panelboard.

(ii) A minimum of three hospital grade duplex outlets shall be conveniently located at the head of each bed. At least two of these duplex outlets shall be on the critical branch of the emergency electrical system.

(iii) One duplex receptacle connected to a normal branch circuit and one duplex outlet connected to the critical branch circuit shall be located on opposite sides of the head of each bed. In addition at least one duplex outlet shall be located on each wall. A dedicated outlet shall be provided at the television location.

(B) Illumination requirements.

(i) Each single patient room and multi-patient wards shall be provided with general lighting and night lighting. General lighting and night lighting shall be controlled at the room entrance. All controls for lighting in patient areas shall be of the quiet operating type. Control of night lighting circuits may be achieved by automatic means and in such instances control of night lighting at the room entrance shall not be required. At least one general light fixture and night lighting shall be powered from the critical branch of the essential electrical system.

(ii) A reading light shall be provided over each patient bed. Reading light control shall be readily accessible from each patient bed. Flexible light arms, if used, shall be mechanically controlled to prevent the bulb from coming in contact with bed linen. High heat-producing light sources such as incandescent and halogen shall be avoided to prevent burns to patients and/or bed linen. Light sources shall be covered with a diffuser or a lens.

(iii) A wall or ceiling-mounted lighting fixture shall be provided above each lavatory.

(iv) A ceiling-mounted fixture shall be provided in patient bathrooms where the lighting fixture above the lavatory does not provide adequate illumination of the entire bathroom. Some form of fixed illumination shall be powered from the critical branch.

(C) Nurses calling systems. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(n) Laboratory suite.

(1) Architectural requirements.

(A) General.

(i) Laboratory facilities and services shall be provided by the hospital such as hematology, clinical chemistry, urinalysis, cytology, anatomic pathology, immunohematology, microbiology, bacteriology and others.

(ii) Each laboratory unit shall meet the requirements of Chapter 11 of NFPA 99 (relating to Laboratories), and Chapter 18 of NFPA 101 (relating to New Health Care Occupancies).

(B) Minimum laboratory facilities. When laboratory services are provided off site by contract, the following minimum facilities shall be provided within the hospital.

(i) Laboratory work room. The laboratory workroom shall include a counter and a sink with hands-free operable controls.

(ii) General storage. Cabinets or closets shall be provided for supplies and equipment used in obtaining samples for testing. A refrigerator or other similar equipment shall be provided for specimen storage waiting for transfer to off-site testing.

(iii) Blood storage facilities. Refrigerated blood storage facilities for transfusions shall be provided. The blood storage

refrigerator shall be equipped with temperature monitoring and alarm signals.

(iv) Specimen collection facilities. A blood collection area shall be provided with a counter, space for seating, and hand washing fixture with hands-free operable controls. A toilet and lavatory with hands-free operable controls shall be provided for specimen collection. This facility may be outside the laboratory suite if conveniently located.

(C) On-site laboratory facilities. When the hospital provides on-site laboratory services, the following facilities shall be provided in addition to the requirements in subparagraphs (A) and (B) of this paragraph.

(i) Laboratory workroom(s). The laboratory work room shall include counter(s), space appropriately designed for laboratory equipment and sink(s) with hands-free operable controls.

(ii) General storage. Storage, including refrigeration for reagents, standards, supplies, and stained specimen microscope slides, etc. shall be provided. Separate facilities shall be provided for such incompatible materials as acids and bases, and vented storage shall be provided for volatile solvents.

(iii) Chemical safety facilities. When chemical safety is a requirement, provisions shall be made for an emergency shower and eye flushing devices.

(iv) Flammable liquids. When flammable or combustible liquids are used, the liquids shall be stored in approved containers, in accordance with National Fire Protection Association 30, Flammable and Combustible Liquids Code, 2003 edition.

(v) Radioactive materials. When radioactive materials are employed, storage facilities shall be provided.

(D) Bone marrow laboratory. A cryopreservation laboratory and a human leukocyte antigen laboratory shall be provided in hospitals providing bone marrow transplantation services.

(E) Service areas and facilities. The following service areas and facilities shall be provided.

(i) Hand washing facilities. Each laboratory room or work area shall be provided with a hand washing fixture(s) with hands-free operable controls.

(ii) Office spaces. The scope of laboratory services shall determine the size and quantity for administrative areas including offices as well as space for clerical work, filing, and record maintenance. At a minimum, an office space shall be provided for the use of the laboratory service director.

(iii) Staff facilities. Lounge, locker, and toilet facilities shall be conveniently located for male and female laboratory staff. These may be outside the laboratory area and shared with other departments.

(iv) Housekeeping room. A housekeeping room shall be located within the suite or conveniently located nearby.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title. Floors in laboratories shall comply with the requirements of §133.162(d)(2)(B)(iii) of this title except that carpet flooring shall not be used.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) No air from the laboratory areas shall be recirculated to other parts of the facility. Recirculation of air within the laboratory suite is allowed.

(B) When laboratory hoods are provided, they shall meet the following general requirements.

(i) The average face velocity of each exhaust hood shall be at least 75 feet per minute.

(ii) The exhaust shall be connected to an exhaust system to the exterior which is separate from the building exhaust system. Biological safety cabinets with HEPA filters and alarms to alert staff do not have to be exhausted to the exterior. If the air changes for biological safety cabinets as provided in Table 3 of §133.169(c) of this title do not provide sufficient air for proper operation of the safety cabinets (when in use), supplementary make-up air (filtered and preheated) shall be provided around these units to maintain the required airflow direction and exhaust velocity. Make-up air system for safety cabinets shall be arranged to minimize "short circuiting" of air and to avoid reduction in air velocity at the point of contaminant capture.

(iii) The exhaust fan shall be located at the discharge end of the system.

(iv) The exhaust duct system shall be of noncombustible and corrosion-resistant material.

(v) Where fume hoods are used, the design should consider the placement and types of air distribution devices to avoid the disturbance of a uniform velocity across the face of the hood.

(C) When special laboratory hoods are provided, they shall meet the following special standards for these types of hoods.

(i) Fume hoods, and their associated equipment in the air stream, intended for use with perchloric acid and other strong oxidants, shall be constructed of stainless steel or other material consistent with special exposures, and be provided with a water wash and drain system to permit periodic flushing of duct and hood. Electrical equipment intended for installation within such ducts shall be designed and constructed to resist penetration by water. Duct systems serving these hoods shall be constructed of acid-resistant stainless steel for at least 10 feet from the hood. Lubricants and seals shall not contain organic materials. When perchloric acid or other strong oxidants are only transferred from one container to another, standard laboratory fume hoods and the associated equipment may be used in lieu of stainless steel construction.

(ii) Each laboratory hood used to process infectious or radioactive materials shall have a minimum face velocity of 90-110 feet per minute, be connected to an independent exhaust system, with suitable pressure-independent air modulating devices and alarms to alert staff of fan shutdown or loss of airflow. Each hood shall also have filters with a 99.97% efficiency (based on the dioctyl-phthalate (DOP) test method) in the exhaust stream, and be designed and equipped to permit the safe removal, disposal, and replacement of contaminated filters. Filters shall be as close to the hood as practical to minimize duct contamination.

(iii) Fume hoods intended for use with radioactive isotopes shall be constructed of stainless steel or other material suitable for the particular exposure and shall comply with National Fire Protection Association 801, Standard for Facilities Handling Radioactive Materials, 2003 edition and NFPA 99, §11.3.5.

(iv) Each laboratory hood shall have a suitable pressure-independent air modulating device and alarm to alert staff of fan shutdown or loss of airflow. The alarm shall be audible within the laboratory and at a 24-hour manned location.

(D) Filtration requirements for air handling units serving the laboratory suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title.

(E) Duct linings exposed to air movement shall not be used in ducts serving any laboratory room and clean room unless terminal filters of at least 80% efficiency are installed downstream of linings. This requirement shall not apply to mixing boxes and acoustical traps that have special coverings over such lining.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) General.

(i) Faucet spouts at lavatories and sinks shall have clearances adequate to avoid contaminating utensils and the contents of beakers, test tubes, etc.

(ii) Drain lines from sinks used for acid waste disposal shall be made of acid-resistant material.

(iii) Drain lines serving some types of automatic blood-cell counters must be of carefully selected material that will eliminate potential for undesirable chemical reactions (and/or explosions) between sodium azide wastes and copper, lead, brass, and solder, etc.

(B) Medical gas systems. When provided, medical gas systems shall comply with §133.162(d)(4)(A)(iii) and (iv) of this title. The number of outlets in the laboratory for vacuum, gases, and air shall be determined by the functional program requirements.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(A) The blood storage refrigerator shall have an alarm device to indicate a temperature increase or malfunction and indicate an audible warning at a 24-hour manned location.

(B) The blood storage refrigerator shall be connected to the critical branch of the emergency essential electrical system.

(C) All exhausts hoods shall be connected to the emergency essential electrical system.

(o) Laundry suite. Laundry facilities shall be provided on site or off site. On-site laundry services may be within the hospital or in a separate building on-site. The laundry facilities shall be separated from patient rooms, areas of food preparation and storage, and areas in which clean supplies and equipment are stored.

(1) Architectural requirements.

(A) When laundry service is provided on site, it shall comply with the following.

(i) Soiled and clean linen processing rooms shall be provided. When the soiled and clean linen processing are combined in a single room, each process shall be physically separated within the room.

(ii) Adequate hand washing facilities shall be provided in both the soiled and clean processing areas.

(iii) A receiving, holding, and sorting room for control and distribution of soiled linen shall be provided. This area may be combined with the soiled linens processing room. Discharge from soiled linen chutes may be received in the soiled room/area or in a separate dedicated room.

(iv) A laundry processing room shall be provided with a commercial washer(s) and dryer(s) capable of processing at least a seven-day laundry supply within the regular scheduled work week.

(v) A clean linen processing room/area shall be provided with folding counters or tables. This area shall have provisions for inspections, folding, packing and mending of linen.

(vi) A holding room or area for storage and issuing of clean linen shall be provided but may be combined with clean linen processing room.

(vii) Storage space and cabinets for soaps, stain removers, and other laundry processing agents shall be located in the soiled and clean processing room/areas.

(viii) Laundry equipment shall be arranged so that the processing of laundry is an orderly work flow from soiled to clean operations. Cross-traffic shall be held to a minimum to prevent contamination.

(B) When laundry service is provided off site, the following minimum requirements shall be provided on site:

(i) a service entrance which shall have a drive under canopy for protection from inclement weather, for loading and unloading of linen;

(ii) a control station for pickup and receiving. This may be a room at the common loading dock, in the soiled linen holding room, or the central clean linen storage room;

(iii) a soiled linen holding room; and

(iv) a central clean linen storage/issuing room in addition to linen storage required at the individual patient units.

(C) The following areas/rooms shall be provided regardless of delivery type of laundry service:

(i) office space for the director of laundry services;

(ii) cart storage rooms for clean and soiled linen. The cart storage areas may be provided within the clean and soiled rooms. Carts may not be parked or stored in the egress corridor;

(iii) cart sanitizing facilities which comply with subsection (b) of this section;

(iv) staff toilet in the laundry suite or convenient for staff use and with a hand washing fixture with hands-free operable controls;

(v) lockers for staff use may be in laundry suite or part of a central locker room when convenient to the laundry; and

(vi) housekeeping room within the laundry suite or available near by.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) The ventilation system shall include adequate intake, filtration, exchange rate, and exhaust in accordance with Table 3 and Table 4 of §133.169(c) and (d) of this title, respectively.

(B) Filtration requirements for air handling units serving the laundry suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title.

(C) Direction of air flow of the HVAC systems shall be from clean to soiled areas.

(D) The ventilation system for soiled processing area shall have negative air pressure while the clean processing area shall have positive pressure.

(E) Lint interceptors shall be located outside the laundry area. Drainage piping that serves laundry equipment shall employ suds-control features.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(p) Medical records suite.

(1) Architectural requirements. The following rooms, areas, or offices shall be provided in the medical records suite:

(A) medical records administrator or technician office;

(B) review and dictating rooms or spaces;

(C) work area which includes provisions for sorting, recording, scanning, or microfilming records; and

(D) file room. When nondigital files are stored on site, the room shall be considered as hazardous. The construction protection for the storage room or area shall comply with Chapter 18 of NFPA 101, §18.3.2.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(q) Mental health and chemical dependency nursing suite.

(1) Architectural requirements. When mental health and chemical dependency patient care services are provided, the suite shall comply with the requirements contained in subsection (t)(1) of this section and the requirements of this paragraph.

(A) A minimum of two separate social spaces, one appropriate for noisy activities and the other for quiet activities, shall be provided. The combined total area shall be not less than 40 square feet per bed with not less than 120 square feet for each of the two spaces, whichever is greater.

(B) A room for group therapy shall be provided. The room shall not be less than 250 square feet. The group therapy room may be combined with the quiet space required in subparagraph (A) of this paragraph when the unit accommodates not more than 12 patients.

(C) Space shall be provided for occupational therapy at the rate of 15 square feet per bed with a minimum total area of 200 square feet, whichever is greater. Space shall include hand washing, work counters, storage, and displays. When the mental health and chemical dependency nursing unit contains less than 12 beds, the occupational therapy functions may be performed within the noisy activities area, if at least 10 additional square feet per patient served is included.

(D) A consultation room for each 12 beds or any portion thereof shall be provided. Each consultation room shall have a minimum floor space of 100 square feet. Each room shall be designed for acoustical and visual privacy.

(E) There shall be a suite in each nursing unit for mental health and chemical dependency patients intended for short-term occupancy by a single person requiring security and protection from self or others. The seclusion suite shall consist of seclusion room(s), an anteroom or a vestibule, and a toilet.

(i) Each seclusion room shall be located and designed in a manner affording direct visual supervision by nursing staff and shall be constructed to prevent patient hiding, escape, injury, or suicide. There shall be a minimum of one seclusion room for each 24 beds or any portion thereof.

(I) The floor area of each seclusion room shall be not less than 60 square feet. The minimum room dimension shall be 6 feet.

(II) The seclusion room shall have a minimum ceiling height of 9 feet.

(III) The door to each seclusion room shall have no hardware on the room side and shall open out. A vision panel shall be provided in each door to permit staff observation of the entire room while maintaining privacy from the public and other patients.

(IV) Each seclusion room shall have natural light (skylight or window) in order to maintain a therapeutic environment. Skylight wells or windows shall be not less than 400 square inches in area.

(ii) Access to the seclusion room from any public space such as a corridor shall be through an anteroom. When the seclusion suite is directly accessible from the nurse station, a vestibule may be provided in place of an anteroom. A cased opening to the vestibule in lieu of a door may be provided as long as the arrangement assures privacy from the public and other patients.

(I) At least one dimension of the anteroom or vestibule shall be 8 feet.

(II) The door to the anteroom shall swing out.

(iii) There shall be at least one toilet room directly accessible from the anteroom or vestibule.

(I) The toilet room shall be a minimum of 50 square feet.

(II) The toilet room door shall swing out into the anteroom or vestibule.

(III) A water closet and hand washing facilities shall be provided in the toilet room. An unbreakable wall hung mirror may be provided.

(F) When a smoking room is provided, all air shall have a dedicated exhaust system to the exterior.

(G) Service areas shall be provided in accordance with the requirements of subsection (t)(1)(F) of this section and the following additional requirements.

(i) Nurses and doctor's charting areas shall be provided with separation needed for acoustical privacy as well as space required for the function. A view window to permit observation of patient area by the charting nurse or physician may be used provided that it is located so that patient files cannot be read from outside the charting space.

(ii) A small kitchen for patient use shall be provided. It shall contain a sink, refrigerator, kitchen cabinets, ice dispenser, and a microwave. This kitchen may serve as a nourishment center for patients between meals. It may be located in the noisy activity area.

(iii) Patient laundry facilities with automatic washer and an electric dryer shall be provided. This requirement may be omitted in nursing units intended only for adolescent and gero-psychiatric patients.

(2) Details and finishes. Details and finishes in each mental health and chemical dependancy nursing unit shall comply with the requirements contained in subsection (t)(2) of this section and this paragraph.

(A) Details.

(i) The type and degree of security and patient safety required in the suite shall be determined by hospital administration and described in the hospital's functional program narrative, unless stated otherwise within these rules.

(ii) All areas of the mental health suite, including entrances to patient rooms, shall be visible from the nurse station(s). Observation by video cameras of seclusion rooms, entrances, hallways, and activity areas shall be acceptable.

(iii) All exposed and accessible fasteners shall be tamper-resistant.

(iv) Suitable hardware shall be provided on doors to toilet rooms so that access to these rooms can be controlled by staff. Hardware shall be utilized which is appropriate to prevent patient injury.

(v) Only breakaway or collapsible clothes bars in wardrobes, lockers, and closets and shower curtain rods shall be permitted in nursing units for mental health and chemical dependency patients.

(vi) Wire coat hangers shall not be permitted in the suite.

(vii) Special fixtures, hardware, and tamper-proof screws are required throughout the suite.

(viii) Horizontal grab bars shall be constructed to prevent looping or tying of cords, ropes, etc.

(ix) Where glass fragments may create a hazard, safety glazing or other appropriate security features shall be incorporated.

(B) Finishes. Patient sleeping rooms, patient toilet rooms and seclusion rooms shall have monolithic ceilings and bonded walls for patient safety and security measures. The ceiling in the soiled workroom shall be monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title. Gero-psychiatric patient rooms and toilet rooms may omit the monolithic ceiling requirement when hospital administration provides a written statement (on hospital letterhead) that the type and degree of security is appropriate for the patient areas.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with subsection (t)(3) of this section and this paragraph.

(A) Special consideration shall be given to the type of heating and cooling units, ventilation outlets, and appurtenance installed in patient-occupied areas of mental health nursing units. The following shall apply:

(B) All air grilles and diffusers shall be of a type that prevents the insertion of foreign objects.

(C) All convector or HVAC enclosures exposed in the room shall be constructed with rounded corners and shall have enclosures fastened with tamper-resistant fasteners.

(D) HVAC equipment shall be of a type that minimizes the need for maintenance within the room.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with subsection (t)(4) of this section and this paragraph.

(A) Piping systems.

(i) Piped medical gas systems are not required.

(ii) Only tamper-proof sprinkler and tamper-proof showerheads from which it is not possible to suspend any objects shall be installed.

(B) Plumbing fixtures.

(i) Faucet controls shall not be equipped with handles that may be easily broken off.

(ii) Bedpan washers are not required in patient bathrooms.

(5) Electrical requirements. Electrical requirements shall be in accordance with subsection (t)(5) of this section and this paragraph.

(A) A nurses calling system is not required in patient rooms. However, when a nurses calling system is provided, the system shall meet the requirements of §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title. Pull cords shall not exceed 18 inches in length, and provisions shall be made to permit removal of call buttons and use of blank plates as required for security.

(B) Each patient room shall have duplex grounded receptacles. There shall be one receptacle at each side of the head of each bed and one on every other wall. Receptacles in areas intended for mental health and chemical dependency patients of all ages shall be protected by GFCI breakers installed in distribution panel enclosures serving the unit.

(C) Fifteen-ampere and 20-ampere, 125-volt receptacles intended to supply patient care areas shall be tamper-resistant as permitted by NFPA 70, §517-18, or shall be protected by GFCI breakers. A tamper-resistant receptacle is one that is constructed to limit improper access to its energized contacts.

(r) Morgue.

(1) Architectural requirements.

(A) General. When a morgue or body-holding room is provided, it shall be located to avoid the need for transporting bodies of deceased patients through public areas. A body-holding room shall be provided as a minimum for a general hospital.

(B) Autopsy performed within hospital. When autopsies are performed within the hospital, the following rooms, areas, and equipment shall be provided.

(i) Refrigerated facilities shall be provided for body-holding.

(ii) The autopsy room shall contain work counters, hand washing facilities with hands-free operable controls, autopsy table and storage space for supplies, equipment and specimens.

(iii) A deep sink shall be provided for washing specimens.

(iv) A clothing change area shall be provided with shower, toilet, hand washing facilities and lockers.

(C) Service areas. The following service areas shall be provided:

(i) a pathologist office;

(ii) staff toilets. Toilets may be outside the suite but be convenient for staff use with hand washing fixture(s) with hands-free operable controls; and

(iii) a housekeeping room. A housekeeping room which meets the requirements of §133.162(d)(2)(A)(xxviii) of this title shall be provided for the exclusive use of the morgue when autopsies are performed.

(D) Minimum requirements. If autopsies are performed outside the hospital, a well-ventilated, temperature-controlled, nonrefrigerated body-holding room shall be provided.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Flooring used in the autopsy room shall be the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(B) Ceilings in the autopsy rooms shall be monolithic as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) The autopsy room shall be equipped with low exhaust grilles.

(B) The body-holding room shall be ventilated in accordance with Table 3 of §133.169(c) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph. Refrigerators for body-holding in the autopsy room shall be connected to the equipment branch of the essential electrical distribution system.

(s) Nuclear medicine suite.

(1) Architectural requirements.

(A) General. When nuclear medicine services are provided, the facilities may be in a separate suite or combined with an imaging suite.

(i) When nuclear medicine requires radiation protection, a medical physicist licensed under the Texas Medical Physics Practice Act, Occupations Code, Chapter 602, shall specify the type, location, and amount of radiation protection to be installed for the layout, equipment selections and storage, handling and disposal of radioactive material.

(ii) The nuclear medicine room shall be sufficiently sized to house all fixed and moveable equipment and allow a minimum of three feet of clear and unobstructed working space on all sides of equipment accessible to staff and patient.

(B) Radioisotope room (Hot lab). When radiopharmaceutical preparation is performed on site, the room shall include sufficient space for equipment, storage of radionuclides, chemicals for preparation, dose calibrators, and record keeping. When preprepared materials are used, storage and calculation area may be smaller than for on-site preparation.

(i) The room and isotope handling areas within the room shall have appropriate radiation shielding.

(ii) There shall be a shielded area or enclosed shielded cabinet for long-term storage of decaying radioisotopes.

(iii) When venting of radioactive gases is required, a hood shall exhaust to the exterior.

(C) Positron emission tomography (PET). When PET services are provided, scanner and cyclotron rooms shall be in compliance with the manufacturer's recommendations and provide a minimum of three feet of clear and unobstructed working space on all sides of equipment accessible to staff and patient.

(i) A control alcove shall be provided with a view window permitting view of the patient.

(ii) An equipment area large enough to contain necessary electronic and electrical gear shall be provided.

(iii) A dose administration room(s) with radiation shielding shall be located near the treatment room. Patients in route to procedure rooms shall not pass through public corridors and waiting rooms after injection with radioisotope.

(iv) A patient toilet with radiation shielding shall be provided with or adjacent to dose administration room(s). The patient toilet room shall contain a hand washing fixture with hands-free operable controls.

(D) Service areas.

(i) Patient waiting area. The area shall be out of traffic and under direct staff visual control. When the waiting area serves both outpatients and inpatients, separate areas shall be provided and include visual privacy between the waiting areas.

(ii) Control desk and reception area. A control desk and reception area shall be provided.

(iii) Dictation and report preparation area. The dictation and report preparation area may be incorporated with the control station.

(iv) Holding area. The holding area shall be under direct staff control, out of the direct line of traffic, and have space for stretchers. The holding area shall accommodate two stretchers for the first procedure room with one additional station for each additional procedure room.

(v) Patient toilet facilities. A toilet room with a hand washing fixture with hands-free operable controls shall be provided convenient to the waiting room and procedure room.

(vi) Staff toilet facilities. Toilets and hand washing fixtures with hands-free operable controls may be outside the suite but shall be convenient for staff use.

(vii) Patient dressing rooms or cubicles. Dressing rooms or cubicles shall be provided convenient to the waiting areas and procedure rooms. Each room or cubicle shall include a seat or bench, mirror, and provisions for hanging patients' clothing and for securing valuables. At least one dressing room shall be provided to accommodate wheelchair patients.

(viii) Exam room(s). When examination rooms are provided, each room shall have a minimum of 100 square feet of clear

floor area exclusive of built-in shelves or cabinets. Each exam room shall be equipped with a work counter and a hand washing fixture with hands-free operable controls.

(ix) Dose administration area. When a dose administration area is provided, the area shall be located near the preparation area and include visual privacy for the patients.

(x) Computer control area/room. Computer control area shall be located within or adjacent to the treatment room(s). When a centralized computer area is provided, it shall be a separate room with access terminals available within the treatment rooms.

(xi) Film processing room. A darkroom shall be provided for film processing unless the processing equipment normally used does not require a darkroom for loading and transfer. When daylight processing is used, the darkroom may be minimal for emergency and special uses. Film processing shall be located convenient to the treatment room(s) and to the quality control area.

(xii) Quality control area or room. A quality control area shall include view boxes illuminated with light of the same color value and intensity.

(xiii) Film storage room (active). A room with cabinet or shelves for filing patient film for immediate retrieval shall be provided.

(xiv) Film storage room (inactive). A room for inactive film storage may be located outside the nuclear medicine suite, but must be under the administrative control of nuclear medicine personnel and properly secured to protect films against loss or damage.

(xv) If digital imaging is utilized throughout the suite, the darkroom film processing area and film viewers may be omitted.

(xvi) Storage for unexposed film. Storage facilities for unexposed film shall include protection of film against exposure or damage.

(xvii) Offices for physicians, oncologist, physicists, and assistants. Offices shall include provisions for individual consultation, viewing, and charting of film.

(xviii) Clerical office(s) spaces. Clerical office(s) spaces shall be provided.

(xix) Consultation room. A consultation room shall be provided.

(xx) Clean storage room. A clean storage room shall be provided for clean supplies and linens. A hand washing fixture shall be provided with hands-free operable controls. When conveniently located, the clean storage room may be shared with another department.

(xxi) Soiled workroom. The soiled workroom shall not have direct connection to the nuclear medicine procedure or diagnostic rooms or sterile activity rooms. The room shall contain a clinical sink or equivalent flushing type fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and soiled linen receptacle. When contaminated soiled material or fluid waste is not handled, only a soiled holding room is required.

(xxii) Housekeeping room. The housekeeping room shall be located within the suite.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Radiation protection shall be designed, tested and approved by a medical physicist licensed under the Texas Medical Physics Practice Act, Occupations Code, Chapter 602.

(I) Room shielding calculations for the stipulated rooms within the nuclear medicine suite must be submitted to the Department of State Health Services, Radiation Control (RC) for approval prior to use. Shielding in diagnostic radiographic rooms will be reviewed by RC inspectors, in the field, subsequent to use. Any changes in design or shielding which affects radiation exposure levels adjacent to those rooms, requires prior approval by RC.

(II) Facility design and environmental controls associated with licensable quantities of radioactive material in laboratories or procedure rooms must be approved by RC prior to licensed authorizations.

(ii) The nuclear medicine treatment rooms shall have ceiling heights not less than nine feet. Ceilings containing ceiling-mounted equipment shall be of sufficient height to accommodate the equipment of fixtures and their normal movement.

(B) Finishes.

(i) Flooring used in the nuclear medicine procedure room, any work or treatment areas where radioactive material is handled, and soiled workroom shall be of the seamless monolithic type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Ceilings in radiopharmacy, hot laboratory, and soiled workrooms shall be monolithic as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) When radiopharmaceutical preparations are performed, vents and traps for radioactive gases shall be provided.

(B) Direction of air flow of the HVAC system shall be from nonradioactive spaces into the radioactive spaces. A minimum of two return air inlets located diagonally opposite from one another and near floor level shall be provided.

(C) In the PET suite, special ventilation systems together with monitors, sensors, and alarm systems shall be required to vent gases and chemicals. The ventilation shall be directly to the exterior.

(D) Filtration requirements for air handling units serving the nuclear medicine suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title.

(E) Where fume hoods are used, the design should consider the placement and types of air distribution devices to avoid the disturbance of a uniform velocity across the face of the hood. Fume hoods shall be exhausted directly to the exterior.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) Each nuclear medicine procedure room shall have at least four duplex electrical hospital grade receptacles.

(ii) Nuclear medicine procedures rooms shall have general lighting in addition to that provided by special lighting units at the procedure tables.

(B) Nurses calling systems. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(t) Nursing unit. The requirements in this subsection apply to nursing units in hospitals for all types of inpatient care. Facilities providing care to less than 15 pediatric inpatients may be included with an adult nursing unit. Additional requirements for a nursing unit providing care to 15 or more pediatric patients are contained in subsection (w) of this section.

(1) Architectural requirements. Architectural requirements shall be in accordance with §133.162(d)(1) of this title and this paragraph.

(A) Handicapped accessibility requirements. At least 10% of each patient room type, isolation room, bathing units and toilets in medical/surgical, intermediate care, universal care, antepartum, postpartum, mental health, chemical dependency, and pediatric nursing units and all public and common use areas shall be designed and constructed to be handicapped accessible. These requirements shall apply in all new construction and when an existing nursing unit or a portion thereof is converted from one service to another, i.e. mental health care to medical or surgical nursing care.

(B) Patient room suites. A patient room suite shall consist of the patient room and a bathroom. Patient room suites shall comply with the following requirements.

(i) Maximum patient room capacity. The maximum patient room capacity shall be two patients. In existing facilities where renovation work is undertaken and the present capacity is more than two patients, the maximum room capacity shall be no more than the present capacity with a maximum of four patients.

(ii) Single-bed patient room. In a single-bed patient room, the minimum clear floor area shall be 120 square feet.

(iii) Multi-bed (two) patient room. The clearance between the side of a bed and a wall/partition shall be a minimum of three feet. The clearance between sides of beds shall be a minimum of five feet. The minimum distance at the foot of the bed shall not be less than four feet for a single load area/room or seven feet for a double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds. The requirements of this clause are illustrated in Table 8, Diagram G of §133.169(h) of this title.

(iv) Multi-bed (two) accessible patient room. The clearance between the side of a bed and a wall/partition shall be a minimum of five feet. The clearance between sides of beds shall be a minimum of four feet. The minimum distance at the foot of the bed shall not be less than four feet for a single load area/room or seven feet for a double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds. The requirements of this clause are illustrated in Table 8, Diagram H of §133.169(h) of this title.

(v) Arrangement of patient rooms. Minor encroachments including columns and wall hung lavatories that do not interfere with functions may be ignored when determining space requirements for patient rooms.

(I) Required clear floor space in patient rooms shall be exclusive of toilet rooms, closets, lockers, built-in cabinets, wardrobes, alcoves, or vestibules.

(II) Visual privacy shall be provided each patient in multi-bed rooms. Design for privacy shall not restrict independent patient access to the corridor, lavatory, or bathroom.

(vi) Patient bathroom. Each patient shall have access to a bathroom without having to enter the general corridor area. Each bathroom shall contain a toilet with bed pan washers, hand washing fixture with hands-free operable controls, bathing facilities, and storage shelf or cabinet and serve not more than two patient rooms. Hand washing facilities shall be located in the patient room and in the patient bathroom. The hand washing fixture in the room shall be located outside of the patient's cubicle curtain in multi-bed patient room.

(vii) Patient storage. Each patient shall have a separate wardrobe, locker, or closet that is suitable for hanging full-length garments and for storing personal effects. A minimum of 12 lineal inches of hanging space shall be provided per patient.

(C) Airborne infection isolation suites. A minimum of one isolation suite shall be provided for each 30 acute care beds or fraction thereof. The suite may be located within a nursing unit or in a separate isolation unit. When a pediatric patient suite is located in an adult nursing unit and is not part of a pediatric or adolescent nursing unit, a minimum of one isolation room shall be designated for pediatric patient care. Each airborne infection isolation suite shall consist of a work area, a patient room, and a patient bathroom.

(i) The work area may be a separately enclosed anteroom or a vestibule that is open to and is located immediately inside the door to the patient room. It shall have facilities for hand washing, gowning, and storage of clean and soiled materials. One enclosed anteroom may serve multiple isolation rooms.

(ii) Each patient room shall have a clear floor area of 120 square feet exclusive of the work area and shall contain only one bed. A patient bathroom shall be provided in accordance with subparagraph (B)(vi) of this paragraph.

(iii) At least one airborne infection isolation suite with an enclosed anteroom shall be provided.

(iv) A door(s) from an anteroom to an airborne infection isolation room(s) and a door(s) from an egress corridor into an anteroom shall be provided with a self-closing device(s). When an isolation room does not have an anteroom, the door from the egress corridor into the isolation room shall be provided with a self-closing device. When sliding doors are used in isolation rooms in CCU suites and in surgical suite post-anesthesia care units, the self-closing device may not be required as long as assurances of negative air pressure are met when sliding doors are opened.

(v) Pressure differential monitors or air flow devices shall be installed outside the isolation room and anteroom. Devices shall be installed in corridors, passageways, etc.

(D) Protective environment suite. When specialized services for patients with extreme susceptibility to infection are provided, spatial requirements for the suite shall be identical to those for airborne infection isolation suites contained in subparagraph (C) of this paragraph with the exception that an enclosed anteroom shall be provided.

(E) Room for disturbed medical patients. Each general hospital shall provide at least one private patient room for patients needing close supervision for medical and/or psychiatric care. The room may be part of the mental health and chemical dependency nursing suite described in subsection (q) of this section. If the room is part of a nursing suite, the provisions of subparagraph (B)(ii) of this para-

graph shall apply. Each room shall be designed in accordance with subsection (q)(2)(A) and (B) of this section.

(F) Service areas. Service areas shall be located in, or readily available to, each nursing unit. Each service area may be arranged and located to serve more than one nursing unit, but at least one service area shall be provided on each nursing floor. The following service areas shall be provided:

(i) an administrative center or nurses station with an adjacent but separate dictation space;

(ii) a nurses office;

(iii) an area for charting. The area may be combined with the nurses station when adequate space is provided for both;

(iv) a medication room, medicine alcove area, or a self-contained medicine dispensing unit under visual control of nursing staff. The medication alcove area may be located in the clean workroom. The self-contained medicine dispensing unit may be located in an alcove at the nurse station. The room, area or unit shall contain a work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances. Standard cup-sinks provided in many self-contained units are not adequate for hand washing;

(v) a nourishment station containing a work counter with sink, microwave, refrigerator and storage cabinets and not located in the clean workroom;

(vi) a multipurpose room for staff and patient conferences, education, demonstrations, and consultation. The room shall be conveniently accessible to each nursing unit and may serve several nursing units or departments. The room may be located on another floor if convenient for regular use;

(vii) a conveniently located examination/treatment room which may serve several nursing units located on the same floor. The room shall have a minimum clear floor area of 100 square feet and contain a counter for writing and hand washing facilities with hands-free operable controls. This room may be omitted if all patient rooms on the floor are single-bed patient rooms;

(viii) special assisted bathing facilities, including space for attendant, for patients on stretchers, carts, and wheelchairs at the ratio of one per 100 beds or a fraction thereof. This may be on another floor if convenient for use. The central bathing room shall contain a bathtub which is accessible to a patient in a wheelchair or a shower that can accommodate a gurney. The room shall have space for drying and dressing and be provided with a hand washing fixture with hands-free operable controls and a toilet with three feet of clear space on sides and front of the water closet;

(ix) staff lounge with unisex dressing cubicles, lockers, toilets and hand washing facilities. These facilities may be on another floor;

(x) securable closets or cabinet compartments for personal articles of nursing unit staff. The closets or lockers shall be located at or near the nurse station. At a minimum, these shall be large enough for purses and billfolds. Coats may be stored in closets or cabinets on each floor or in a central staff locker area;

(xi) clean workroom or clean supply room. When used for preparing patient care items, it shall contain a work counter, hand washing facilities with hands-free operable controls, and storage facilities for clean and sterile supplies. When used only for storage and holding as part of a distribution system of clean and sterile supplies, the work counter and hand washing facilities may be omitted;

(xii) clean linen storage for each nursing unit. This may be within a clean workroom, a separate closet, or an approved distribution system on each floor. If a closed cart system is used, storage may be in an alcove, but must be out of the path of normal traffic and under staff control;

(xiii) a soiled workroom or soiled holding room. The room shall contain a clinical sink or equivalent flushing rim fixture, hand washing facilities with hands-free operable controls, both with hot and cold water. The room shall have a work counter and space for separate covered containers for soiled linen and waste. When facilities for cleaning bedpans are provided elsewhere, the flushing rim clinical sink may be omitted;

(xiv) an equipment storage room or alcove. The room(s) or alcove(s) shall be located on the patient floor to keep the corridor width free of all equipment and supplies. Ten square feet of equipment storage or supplies shall be provided for each patient bed. Combustible supplies shall not be stored in an alcove in the egress corridors;

(xv) an emergency equipment storage room or alcove under direct visual control of the nursing staff;

(xvi) a housekeeping room which may also serve adjacent nursing units;

(xvii) stretcher and wheelchair storage space which is located without restricting normal traffic;

(xviii) public toilets with hand washing facilities. The toilets shall be located on each floor containing a nursing unit;

(xix) staff toilet conveniently located to each nursing unit. At least one staff toilet shall be located on each patient sleeping floor. Toilet may be unisex; and

(xx) an ice dispensing machine for each nursing unit which is located at the nourishment station or the clean work room.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Egress. Means of egress from each patient suite shall comply with the requirements of NFPA 101, §18.2.

(ii) Patient bathroom and toilet room doors. Door leaves to all patient bathrooms and toilet rooms shall be at least 36 inches wide and shall swing outward or be double acting so that nursing staff may gain access to a patient who has collapsed against the door. Doors lockable from the inside shall have hardware that allows staff to open the door from the outside.

(iii) Vision panels. Vision panels shall be provided in the door between an anteroom and an airborne infection isolation room or a protective environment room.

(iv) Patient room windows. Each patient sleeping room shall have an outside door or an outside window. When operable windows are provided and the operation of windows requires the use of tools or keys, the tools or keys shall be located at each nurses station, on the same floor, and easily accessible to staff. The allowable window sill height shall not exceed 36 inches above the floor.

(v) Location of patient room windows. Windows in patient sleeping rooms shall be located on an outside wall. These windows may face an atrium, an inner court, or an outer court provided the following requirements are met.

(I) Patient room atria windows. When patient room windows face an atrium, the atrium shall comply with the requirements of NFPA 101, §8.6.7. When windows are operable, an engineered smoke control system shall be provided in accordance with National Fire Protection Association 92B, Guide for Smoke Management Systems in Malls, Atria, and Large Areas, 2000 edition.

(II) Outer courts. Outer court (not enclosed by building on one side) onto which the required windows open shall have a minimum width, at all levels, of not less than three inches for each foot, or fraction thereof, of the height (average height of enclosing walls) of such court, but in no case shall the width be less than five feet. An outer court shall have a horizontal cross-sectional area not greater than four times the square of its width.

(III) Inner courts. Inner court (enclosed by building on all sides) onto which the required windows open shall have minimum width, at all levels, of not less than one foot for each foot, or fraction thereof, of the height (average height of enclosing walls) of such courts, but in no case shall the width be less than 10 feet. When operable windows are provided, a horizontal, unobstructed, and permanently open air intake or passage having a cross-sectional area of not less than 21 square feet shall be provided at or near the bottom of the court. Metal decorative grilles not effectively reducing the open area by more than 5.0% shall be permitted at the ends. Walls, partitions, floor, and floor-ceiling assemblies forming intakes or passages shall be noncombustible and shall be constructed in accordance with NFPA 101, §18.3.1.1. An inner court shall have a horizontal cross-sectional area of not less than one and one-half times the square of its width.

(vi) Hand washing facilities. Hand washing facilities shall be conveniently located near the nurses station and in the medication area. One lavatory in an open medication area can meet this requirement.

(vii) Elevator lobbies. Elevator lobbies shall be provided in accordance with §133.164 of this title (relating to Elevators, Escalators, and Conveyors).

(viii) Patient's privacy. Cubicle curtains to assure privacy for each patient shall be provided in all multi-bed patient rooms.

(ix) Telephone access. Each patient shall have access to a telephone directly from each bed.

(B) Finishes.

(i) Seamless floors with coved wall bases described in §133.162(d)(2)(B)(iii)(III) of this title shall be provided in soiled workrooms.

(ii) Wall bases in the soiled workroom shall be made integral and coved with the floor, tightly sealed to the wall, constructed without voids that can harbor insects, retain dirt particles, and impervious to water.

(iii) Monolithic ceilings described in §133.162(d)(2)(B)(vi)(III) of this title shall be provided in airborne infection isolation rooms, protective environment rooms, and soiled workrooms.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) Outside air shall be supplied to each patient room by a central air handling unit to provide make-up air for air exhausted from the bathroom in accordance with Note 3 of Table 3 of §133.169(c) of this title.

(B) Each patient room bathroom shall be exhausted continuously to the exterior in accordance with Table 3 of §133.169(c) of this title.

(C) The isolation room exhaust shall be a dedicated system which exhausts all air continuously to the exterior in accordance with Table 3 of §133.169(c) of this title. Multiple isolation rooms may be interconnected to the same exhaust system.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph. Each patient bathroom shall contain a water closet with a bedpan washer, bathtub or shower and a lavatory.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) Electric receptacles in nursing units.

(i) Each receptacle shall be grounded to the reference grounding point by means of an insulated copper grounding conductor.

(ii) Each patient bed location shall be supplied by at least two branch circuits, one from the critical branch of the emergency system as required by NFPA 99, §3-4 and one from the normal system. All branch circuits from the normal system shall originate in the same panelboard.

(iii) One duplex receptacle connected to a normal branch circuit and one duplex outlet connected to the critical branch circuit shall be located on opposite sides of the head of each bed. In addition at least one duplex outlet shall be located on each wall. A dedicated outlet shall be provided at the television location.

(iv) Each examination table shall have access to two duplex receptacles.

(v) Each work table or counter shall have access to one duplex receptacle for every six feet of table or counter space or fraction thereof.

(vi) One duplex receptacle protected with a GFCI shall be installed in the bathroom to permit the use of electrical appliances in front of the mirror.

(vii) Duplex receptacles shall be installed not more than 50 feet apart in corridors and within 25 feet of corridor ends.

(viii) The isolation exhaust system shall be connected to the emergency essential electrical system.

(B) Nurses calling systems. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(C) Illumination requirements.

(i) General illumination requirements. Nursing unit corridors shall have general illumination with provisions for reducing light levels at night. Illumination of corridors for egress purposes shall comply with NFPA 101, §18.2.8 and §18.2.9.

(ii) Illumination of the nurses station. Illumination of the nurses station and all nursing support areas shall include fixtures powered from the critical branch of the emergency electrical system NFPA 99, §4.4.2.2.2.3(3)(d).

(iii) Patient suite lighting.

(I) Each patient room shall be provided with general lighting and night lighting. General lighting and night lighting shall be controlled at the room entrance. All controls for lighting in pa-

tient areas shall be of the quiet operating type. Control of night lighting circuits may be achieved by automatic means and in such instances control of night lighting at the room entrance shall not be required. At least one general light fixture and night lighting shall be powered from the critical branch of the essential electrical system.

(II) A reading light shall be provided for each patient. Reading light control shall be readily accessible from each patient bed. Flexible light arms, if used, shall be mechanically controlled to prevent the bulb from coming in contact with bed linen. High heat-producing light sources such as incandescent and halogen shall be avoided to prevent burns to patients and/or bed linen. Light sources shall be covered by a diffuser or a lens.

(III) A wall or ceiling-mounted lighting fixture shall be provided above each lavatory.

(IV) A ceiling-mounted fixture shall be provided in patient bathrooms where the lighting fixture above the lavatory does not provide adequate illumination of the entire bathroom. Some form of fixed illumination shall be powered from the critical branch.

(u) Obstetrical suite.

(1) Architectural requirements.

(A) General. When obstetrical services are provided, the obstetrical suite shall be located and arranged to preclude unrelated traffic through the suite. Regardless of the clinical model used for labor, delivery, recovery and postpartum, a hospital offering such services shall be able to demonstrate the availability of one room designed, equipped and held in reserve for emergency, caesarean section deliveries. This room shall be located either in the labor and delivery suite or surgical suite.

(B) Caesarean section (c-section) operating room(s). A minimum of one dedicated c-section operating room shall be located in either the obstetrical or surgical suite. This room shall have a minimum clear floor area of 360 square feet with a minimum dimension of 18 feet exclusive of built-in shelves or cabinets. There shall be no direct access between operating rooms.

(C) Delivery room(s). A minimum of one delivery room shall be provided in every obstetrical suite. The delivery room shall have a minimum clear floor area of 300 square feet with a minimum dimension of 16 feet exclusive of fixed and moveable cabinets and built-in shelves. In facilities having only one c-section operating room, the delivery room shall be designed to function as an emergency c-section operating room. When two c-section operating rooms are provided, the delivery room requirement may be omitted.

(D) Infant resuscitation area. An infant resuscitation space shall be provided within the c-section operating room; delivery room; labor, delivery, and recovery room (LDR); and labor, delivery, recovery and postpartum room (LDRP) with a minimum clear floor area of 40 square feet in addition to the required area of each room or may be provided in a separate but immediately accessible room with a clear floor area of 150 square feet.

(E) Labor room(s). A minimum of two labor beds shall be provided for each delivery room. Each labor room shall be designed for one or two beds with a minimum clear floor area of 120 square feet per bed.

(i) An LDR or LDRP may be substituted for a labor room.

(ii) In facilities having only one delivery room, one of the two required labor beds shall be in a separate room with a minimum clear floor area of 160 square feet to serve as an emergency vaginal delivery room. Medical gas outlets shall be the same as for delivery room.

(iii) Each labor room shall contain a lavatory equipped with hands-free operable controls. Each labor room shall have direct access to a toilet room. One toilet room may serve two labor rooms.

(iv) Labor rooms shall be arranged so that doors are visible from a nurses work station.

(v) A minimum of one shower shall be provided for each four labor beds. Each shower room shall contain a toilet and hand washing fixture with hands-free operable controls.

(F) Recovery room(s). Recovery room(s) shall contain not less than two beds. There shall be enough space for baby and crib and a chair for the support person. Visual privacy of the new family shall be provided. LDRs or LDRPs may be substituted for recovery rooms.

(i) In multiple recovery patient stations, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of five feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than eight feet for single load area/room or twelve feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram N of §133.169(h) of this title.

(ii) A nurse station and charting area shall be provided and arranged to permit staff visual observation of recovery beds.

(iii) A work counter, facilities for dispensing medicine, storage for supplies and equipment, and a clinical sink with bedpan-flushing device shall be provided.

(iv) One hand washing fixture with hands-free operable controls shall be provided for every three recovery beds or fraction thereof. Fixtures shall be uniformly distributed.

(v) There shall be cubicle curtains at each station for patient privacy.

(G) Postpartum and antepartum suite. Postpartum and antepartum patient suites shall be provided in accordance with subsection (t)(1)(B) of this section.

(H) LDR.

(i) When provided, each LDR room shall have controlled access and shall be located so that a patient may be transported to the c-section operating room without the need to pass through other functional areas.

(ii) Each LDR room shall be designed for single occupancy and have a minimum clear floor area of 200 square feet exclusive of the infant resuscitation area, built-in shelves or cabinets, alcove, vestibule or other adjoining rooms. The minimum clear room dimension shall not be less than 11 feet.

(iii) A hand washing fixture with hands-free operable controls shall be provided in each LDR room.

(iv) Each LDR shall have direct access to and exclusive use of a bathroom with a shower, or tub with shower, hand washing fixture with hands-free operable controls and a toilet.

(I) LDRP. When provided, each LDRP room shall have controlled access and shall be located on an exterior wall and have

a window in accordance with subsection (t)(2)(A)(iv) and (v) of this section.

(i) Each room shall be designated for single occupancy and have a minimum clear floor area of 260 square feet exclusive of the infant resuscitation area, built-in shelves or cabinets, alcove, vestibules, or other adjoining rooms. The minimum clear room dimension shall not be less than 11 feet.

(ii) A hand washing fixture with hands-free operable controls shall be provided in each LDRP room.

(iii) Each LDRP shall have direct access to and exclusive use of a bathroom with a shower, or tub with shower, hand washing fixture with hands-free operable controls and a toilet.

(J) Isolation rooms. When patients who have airborne infectious diseases are treated, an isolation room shall be provided in the obstetrical suite which complies with the functional space requirements as specified in subparagraphs (G) - (I) of this paragraph, and with the ventilation requirements for infection isolation rooms in Table 3 of §133.169(c) of this title.

(K) Nursery suite. One infant station for each LDRP and each postpartum bed shall be provided in the nursery. Nurseries shall be located and arranged convenient to the postpartum nursing unit and near or part of the obstetrical suite. The nurseries shall be located and arranged to preclude the need for nonrelated pedestrian traffic. Each nursery unit shall meet the following requirements.

(L) Full-term nursery. A full-term nursery shall have a maximum of 16 infant stations. The clearance between the side of a bassinet and a wall/partition shall be a minimum of two feet six inches. The clearance between sides of bassinets shall be a minimum of four feet. The minimum distance at the foot of the bassinet shall not be less than five feet for single load area/room or seven feet for double load area/room. Three feet of the passage space at the foot of the bassinet may be shared between two bassinets. The requirements of this subparagraph are illustrated in Table 8, Diagram I of §133.169(h) of this title. Additional area shall be provided to accommodate workroom functions if these are located within the nursery area as specified in subparagraph (N)(iv) of this paragraph.

(i) When a rooming-in program is used, the total number of bassinets in full-term nursery units shall be not less than one bassinet for every two LDRP and postpartum beds.

(ii) When a rooming-in program is used but all infants are returned to the nursery at night, a reduction in bassinets shall not be allowed.

(iii) There shall be one lavatory with hands-free operable controls for each six infant stations or fraction thereof. Fixtures shall be uniformly distributed but not in the clear floor area of the infant stations.

(iv) An observation window to permit the viewing of infants from public areas shall be provided. The public viewing areas shall not encroach into the egress corridor.

(M) Continuing care nursery suite. Hospitals with 25 or more maternity beds shall provide a continuing care nursery for infants requiring close observation. The suite shall have a maximum of 16 infant stations. The clearance between the side of the bassinet and a wall/partition shall be a minimum of three feet. The clearance between sides of bassinets shall be a minimum of six feet. The minimum distance at the foot of the bassinet shall not be less than six feet for single load area/room or nine feet for double load area/room. Three feet of the passage space at the foot of the bassinet may be shared between two bassinets. The requirements of this subparagraph are illustrated in Table 8, Diagram J of §133.169(h) of this title. Additional area shall be provided to accommodate workroom functions if these are located within the nursery area as specified in subparagraph (N)(iv) of this paragraph.

(i) The continuing care nursery shall be located on an exterior wall and shall have a window(s). In the nursery, one window may serve more than one bassinet. The window sill height shall not exceed five feet above the floor. Bassinets shall not be located more than 50 feet from an exterior window. A newborn's view to outside windows shall be direct. When partitions are used, the newborn's view to the outside windows may be through no more than two separate clear vision panels.

(ii) The continuing care nursery shall not be located within a full-term nursery.

(iii) There shall be a minimum of one lavatory with hands-free operable controls for each four infant stations or fraction thereof. Fixtures shall be uniformly distributed but not in the clear floor area of the infant stations.

(N) General requirements for nurseries. Each nursery regardless of type shall meet the following requirements:

(i) Observation windows to permit the viewing of infants from public areas for full-term nurseries and from workroom(s) into adjacent nurseries shall be provided. Windows between nurseries may be provided for the convenience of staff observation.

(ii) Ten square feet per bassinet shall be provided for convenient, accessible storage for linens, infant supplies, and equipment.

(iii) A room for consultation, demonstration, breast feeding or breast pumping shall be provided convenient to the unit. A counter with sink with hands-free operable controls, refrigeration and freezer, storage for pump and attachments, and educational materials shall be provided in or convenient to the room.

(iv) Each nursery room shall be served by a connecting workroom(s). The workroom shall contain scrubbing and gowning facilities at the entrance for staff and housekeeping personnel, work counter, refrigerator, storage for supplies, and hand washing fixture with hands-free operable controls. One workroom may serve no more than two nursery rooms provided that required services are convenient to each. No nursery shall open directly into another nursery.

(v) The workroom serving the full-term and continuing care nurseries may be omitted if equivalent work and storage areas and facilities, including those for scrubbing and gowning, are provided within that nursery at the entrance. Space required for work areas located within the nursery is in addition to the area required for infant care. Adequate provisions shall be made for storage of emergency carts and equipment, and for sanitary storage and disposal of soiled waste for the nursery.

(vi) Charting and dictation facilities shall be provided for physicians and nurses. This may be in a separate room or part of the workroom.

(vii) An examination/treatment room or space shall be provided and shall contain a work counter, storage, and lavatory equipped for hand washing with hands-free operable controls. The examination/treatment room or space shall have a minimum clear area of 80 square feet in addition to the required area of each workroom exclusive of fixed and movable cabinets and shelves. The examination treatment space shall be located within the nursery.

(viii) An airborne infection isolation room is required in at least one level of nursery care and the neonatal critical care unit. The isolation room shall be enclosed and separated from the nursery unit with provisions for observation of the infant from adjacent nurseries or control area(s). The minimum size of the room shall be 120 square feet of clear floor area. The isolation room shall contain cabinets, a work counter, and a hand washing fixture with hands-free operable controls. Fixed and moveable cabinets and shelves shall not encroach upon bed/gurney clear floor space/area. The isolation room shall comply with the ventilation requirements in Table 3 of §133.169(c) of this title.

(ix) A housekeeping room shall be provided for the exclusive use of the nursery.

(O) Neonatal critical care unit (NCCU). When an NCCU is provided, the unit shall comply with the following.

(i) The NCCU shall be conveniently located near the obstetrical suite and be arranged to preclude unrelated traffic.

(ii) Each room and ward shall be located on an exterior wall and shall have a window. In a ward, one window may serve more than one patient. The window sill height shall not exceed five feet above the floor. Patient beds shall not be located more than 50 feet from an exterior window. Patients' views to outside windows shall be direct. When partitions are used, the patient's direct view to the exterior may be through no more than two separate clear vision panels. Window shall be in accordance with subsection (t)(2)(A)(v) of this section.

(iii) The NCCU shall have a clearly identified public entrance and reception area arranged to permit visual observation and contact with all traffic entering the unit. Gowning facilities, lockers, and scrub area shall be provided at each public entrance to the patient care area(s) of the NCCU. All scrub sinks shall be provided with hands-free operable controls and large enough to contain splashing.

(iv) A control station shall be provided in a central area and shall have space for counters and storage, and shall have convenient access to a hand washing fixture with hands-free operable controls. The control station may be combined with or include centers for reception, communication and patient monitoring.

(v) NCCU patients may be housed in private rooms or a room with multiple bassinets or cribs. Each unit shall not exceed 24 bassinets or cribs. There shall be at least one enclosed private room for every six bassinets or cribs.

(vi) A single-bassinet/crib patient NCC room shall have a minimum clear floor area of 120 square feet per bassinet/crib exclusive of work counter, vestibule, sink and aisle. A minimum of 12 feet width shall be provided for the head wall for each bed.

(vii) In a multiple-bassinet/crib room/ward the clearance between the side of a sleeping unit and a wall/partition shall be a minimum of five feet. The clearance between sides of sleeping units shall be a minimum of eight feet. The minimum distance at the foot of the bassinet shall not be less than ten feet for single load area/room or sixteen feet for double load area/room. Four feet of the passage space at the foot of the bassinet may be shared between two bassinets. The fixed and moveable cabinets and shelves shall not encroach upon the bassinet/crib clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram K of §133.169(h) of this title.

(viii) A minimum of one isolation room shall be provided with a minimum clear floor area of 120 square feet per bassinet/crib exclusive of work counter, vestibule, sink and aisle. A minimum of 12 feet width shall be provided for the head wall for each bed. A toilet room is not required.

(ix) A lavatory equipped for hand washing with hands-free operable controls shall be provided in each single-bed room. In rooms with multiple beds, one lavatory with hands-free operable controls for each four patient stations or fraction thereof shall be provided. These lavatories shall be located convenient to infant stations.

(x) Each NCCU shall be served by a connecting workroom containing gowning facilities at the entrance for staff and housekeeping personnel, a work space with counter, storage facilities, a lavatory or sink equipped for hand washing with hands-free operable controls, and individual closet or lockers for personal effects of nursing personnel. One workroom may serve not more than two NCCUs.

(xi) A storage space for infant formula shall be provided. This functional space may be outside the NCCU but shall be available for use at all times.

(xii) A breast feeding or pump room shall be provided convenient to the unit. Provision shall be made, either within the room or conveniently located nearby, for a sink with hands-free operable controls, counter, refrigeration and freezer, storage for pump and attachments, and educational materials.

(xiii) A room(s) shall be provided within the NCCU for parents and infants for extended private time together and the room is not considered a patient room. The room(s) shall have direct access to toilet facilities and a hand washing fixture with hands-free operable controls. The room(s) shall have a sleeping area for at least one parent, and sufficient space for the infant's bassinet/crib and equipment. The room(s) shall have electrical and medical gas outlets as specified for NCCU bassinet/cribs. This room(s) shall have direct communication with the NCCU staff.

(xiv) Twenty square feet of equipment storage shall be provided for each patient station. The storage areas shall be out of the way of the corridor traffic.

(xv) Charting and dictation space shall be provided for physicians and nurses.

(xvi) A respiratory therapy work area and storage room shall be provided.

(xvii) Blood gas lab facilities shall be immediately accessible to the NCCU.

(xviii) A staff lounge shall include toilet facilities with a hand washing fixture with hands-free operable controls. The lounge(s) shall be located so that staff may be recalled quickly to the patient area in emergencies. Toilet facilities may be shared as long as privacy is maintained for changing areas.

(xix) Physicians and other staff on 24-hour on-call work schedules shall be provided with sleeping rooms with access to a shower(s), toilet(s), and lavatory(ies). If on-call room(s) are not within the NCCU served, a dedicated telephone or intercom system shall connect the on-call room(s) to the NCCU.

(xx) A waiting room/area shall be provided and contain toilet room(s) with hand washing facilities. Waiting room/area maybe shared with other waiting room/areas if conveniently located.

(xxi) A consultation room shall be provided, if not provided elsewhere in the suite.

(xxii) A housekeeping room shall be provided exclusively within or immediately adjacent to the NCCU. It shall not be shared with other nursing units or departments.

(P) Infant formula facilities. Infant formula facilities shall meet the following requirements.

(i) When infant formula is prepared on site, the infant formula preparation room shall contain a lavatory equipped for hand washing with hands-free operable controls, warming facilities, refrigerator, work counter, formula sterilizer, and storage facilities. The formula room may be located near the nurseries or at another appropriate place within the hospital. Direct access from the formula preparation room to any nursery room is prohibited.

(ii) An infant formula clean-up room shall be provided and include a hand washing fixture with hands-free operable controls, facilities for bottle washing, a work counter, and sterilization equipment.

(iii) When commercial infant formula is used, the separate clean-up and formula preparation rooms may be omitted. The storage and handling may be done in the nursery workroom or in another appropriate room in the hospital that is conveniently accessible at all hours.

(iv) A refrigerated storage and warming facilities for infant formula shall be provided and be accessible for use by nursery personnel at all times.

(Q) Service areas. The following service areas shall be provided to support an obstetrical suite unless otherwise noted.

(i) Control station. The control station shall be located to permit direct visual surveillance of all traffic which enters the obstetrical suite.

(ii) Office. A supervisor's office shall be provided.

(iii) Waiting room/area. A waiting room/area shall be provided and contain toilet room(s) with hand washing facilities, public telephone(s), and drinking fountain(s).

(iv) Scrub facilities. Two scrub stations shall be within 5 feet of the entrance to each c-section operating room and delivery room. Two scrub stations may serve two c-section operating rooms or delivery rooms if the scrub stations are located adjacent to the entrance of each c-section operating room or delivery room. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts. Viewing panels shall be provided for observation of c-section operating rooms and delivery rooms from the scrub area.

(v) Sterilizing facilities. Sterilizing facilities with high speed sterilizers shall be conveniently located to serve all c-section operating rooms and delivery rooms. A work space and a hand washing fixture with hands-free operable controls shall be included. High speed autoclaves should only be used in an emergency situation (e.g. replacements unavailable for dropped instruments). Sterilization facilities would not be necessary when spare instruments are available.

(vi) Anesthesia workroom. An anesthesia workroom shall be provided with work counter, sink with hands-free operable controls, and storage space for small style D or E medical gas cylinders and other anesthesia equipment.

(vii) Medication station. Storage and distribution of medication may be done from a medicine preparation room, medicine alcove area or from a self-contained medicine dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not adequate for hand washing. The medication station may be shared with the clean work room.

(viii) Nourishment station. The nourishment station shall contain sink with hands-free operable controls, work counter, self-dispensing ice machine, refrigerator, cabinets, and not located in the clean work room. Space shall be included for temporary holding of unused or soiled dietary trays. A nourishment station is not required in the nursery suite.

(ix) General storage room(s). A minimum of 50 square feet per operating room is required for general storage space(s). The storage space is exclusive of soiled holding, sterile supplies, clean storage, drug storage, locker rooms. In addition to general storage, equipment storage shall be provided for labor, LDR and LDRP rooms.

(x) Emergency storage. Equipment used for emergencies shall be stored in a room or alcove under direct visual control of the nursing staff.

(xi) Storage alcove. The alcove provided for stretcher storage, portable X-ray equipment, warming devices, auxiliary lamps, etc. shall be located out of direct line of traffic.

(xii) Obstetrical suite staff clothing change rooms. Appropriately sized areas shall be provided for male and female personnel working within the obstetrical suite. These areas shall contain lockers, showers, toilets, hand washing fixtures with hands-free operable controls, and space to change into scrub suits and boots. Separate locker/changing rooms shall be provided for male and female staff. The shower and toilet room(s) may be unisex. These areas shall be arranged to provide a traffic pattern so that personnel entering from outside the obstetrical suite can shower, change, and move directly into the restricted areas of the obstetrical suite.

(xiii) Lounge. A lounge shall be provided in hospitals with four or more obstetrical surgical and delivery rooms. The lounge shall permit staff use without leaving the obstetrical surgical suite or delivery suite and may be accessed from the obstetrical suite staff clothing change rooms or staff changing room for delivery suite. The lounge shall not have direct access from outside the surgical suite. When the lounge is remote from the clothing change rooms, toilet facilities and a hand washing fixture with hands-free operable controls accessible from the lounge shall be provided.

(xiv) Staff toilet facilities. Toilet facilities located in the obstetrical suite for exclusive staff use shall be provided and contain hand washing facilities with hands-free operable controls. The toilet room may be accessible from a staff lounge, when provided.

(xv) Nurses' toilet. A nurses' toilet room shall be provided at the labor and recovery area(s) and shall include hand washing fixture with hands-free operable controls.

(xvi) Dictation and report preparation area. This may be accessible from the lounge area.

(xvii) On-call rooms. Physicians and staff on 24-hour on-call work schedules shall be provided with sleeping rooms with access to a toilet, lavatory and shower. If not contained within the unit itself, the area shall have a telephone or intercom connection to the obstetrical suite(s).

(xviii) Clean workroom or clean supply room. A clean workroom is required. It shall contain a work counter, a hand washing fixture with hands-free operable controls, storage facilities for clean supplies, and a space to package reusable items. The storage for sterile supplies must be in a separated room. When the room is used

only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and hand washing fixture may be omitted.

(xix) Soiled workroom. The soiled workroom shall be for the exclusive use of the obstetrical suite and shall be in addition to the soiled workroom required for the obstetrical surgical suite. The soiled workroom for the obstetrical c-section operating room or delivery room suite shall not have direct connection with operating rooms or other sterile activity rooms. The soiled workroom shall contain a clinical sink with hands-free operable controls or equivalent flushing type fixture, work counter, sink equipped for hand washing, waste receptacle, and linen receptacle. There shall be a designated soiled workroom for the exclusive use of the NCCU.

(xx) Housekeeping rooms. A separate housekeeping room containing a floor receptor or service sink and storage space for housekeeping supplies and equipment shall be provided for the exclusive use of the obstetrical suite, the c-section operating room, and nurseries (one for each).

(xxi) Triage room. When triage services are provided, there shall be a minimum of one triage room in the obstetrical suite.

(I) An obstetrical triage room shall be a minimum clear floor area of 100 square feet with a minimum dimension of nine feet. The obstetrical triage room shall contain cabinets, work counter, examination light, and a hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area.

(II) When a multiple-bed/gurney triage patient station is provided, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed/gurney triage room shall contain cabinets, medication storage, work counter, examination light, and a hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. Privacy shall be provided for each patient with cubicle curtains or movable screens. The requirements of this subclause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(III) A patient in a triage bed shall have access to a patient toilet room without entering the corridor.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) C-section operating rooms and delivery rooms shall have ceiling heights not less than nine feet.

(ii) Recreation rooms, exercise rooms, equipment rooms, and similar spaces where impact noises may be generated shall not be located directly over operating rooms or delivery rooms, unless special provisions are made to minimize such noise as contained in Table 1 of §133.169(a) of this title.

(iii) When vision panels are provided in labor rooms, LDRs, and LDRPs, the windows shall be located, draped, or otherwise arranged to preserve patient privacy from casual observation from outside the labor room.

(iv) Shower controls shall be outside the wet area for use by nursing staff for labor room showers. In the LDRP rooms shower control outside of the wet area may be omitted.

(v) When viewing windows are provided in a NCCU, provision shall be made to control casual viewing of infants.

(vi) Noise control and sound attenuation in a NCCU shall be a design factor and meet the requirements contained in Table 1 of §133.169(a) of this title.

(B) Finishes.

(i) Finishes for LDR and LDRP rooms shall be selected for ease of cleaning and resistance to strong detergents.

(ii) Flooring in c-section operating rooms, delivery rooms, labor rooms, isolation room, and soiled workroom shall be of the seamless type in accordance with the requirements of §133.162(d)(2)(B)(iii)(III) of this title. LDR and LDRP rooms shall have seamless type flooring below the bed and four feet at each side of the bed and foot of the bed.

(iii) Ceilings and walls in c-section operating rooms, delivery rooms, soiled workroom, isolation and anteroom, and sterile processing room shall be of the monolithic type in accordance with §133.162(d)(2)(B)(vi)(III) of this title. Acoustic lay-in ceiling is permissible in the LDR and LDRP rooms.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) The air supply for the c-section operating room and delivery room shall be from ceiling outlets near the center of the work area. Return air shall be from near the floor level. Each c-section operating room and delivery room shall have at least two return air inlets located as remotely from each other as practical. (Design should consider turbulence and other factors of air movement to minimize fall of particulate into a wound site).

(B) Air supply for LDRs, LDRPs, and nurseries shall be from ceiling outlets or high wall outlets. Return air shall be from near the floor level. Each LDR, LDRP, and nursery shall have at least two return air inlets located diagonally opposite from each other.

(C) The ventilation system for anesthesia storage rooms shall conform to the requirements of NFPA 99, §4-3.1.1.2.

(D) Each c-section operating room, delivery room and nursery shall have temperature and humidity indicating devices mounted at eye level.

(E) Air handling units serving the obstetrical and surgical suite shall be equipped with filter having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) General.

(i) Drainage and waste piping shall not be installed within the ceiling or installed in an exposed location in c-section operating rooms and delivery rooms unless special precautions are taken to protect the spaces below from leakage and condensation from necessary overhead piping systems. Any required secondary protection shall be labeled every 20 feet "code required secondary drain system." The labeling shall be in highly visible print.

(ii) Floor drains shall not be installed in c-section rooms and delivery rooms.

(iii) Bedpan-flushing devices shall be installed in all patient toilet rooms serving LDRs and LDRPs.

(B) Medical gas systems. Medical gas systems shall be provided in accordance with §133.162(d)(4)(A)(iii)-(vi) of this title.

(i) Nonflammable medical gas and clinical vacuum outlets shall be provided in accordance with Table 6 of §133.169(f) of this title.

(ii) Nonflammable medical gas and clinical vacuum outlets for the infant resuscitation area or room shall be provided in addition to the required medical gas and vacuum for the mother in accordance with Table 6 of §133.169(f) of this title.

(iii) When a labor room is intended to function as an emergency delivery room the nonflammable medical gas and clinical vacuum outlets shall be provided in accordance with Table 6 of §133.169(f) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) X-ray film illuminators for handling at least four films simultaneously shall be provided in each c-section operating room, labor, and delivery room. When the entire obstetrical suite is provided with digital imaging system capabilities, a minimum of two X-ray film illuminator viewers shall be provided. The film illuminators shall be mounted within the central area of the suite.

(ii) Each c-section operating room shall have at least eight duplex hospital grade receptacles.

(iii) Each delivery room, LDR and LDRP shall have at least six duplex hospital grade receptacles.

(iv) Operating rooms and delivery rooms shall have at least three of the required duplex hospital grade receptacles located convenient to the head of the procedure table.

(v) Newborn and continuing care nurseries shall have one normal and one critical duplex outlet for every two bassinets.

(vi) In the infant resuscitation area or room, three duplex hospital grade receptacles shall be provided for the infant in addition to those required for the mother.

(vii) The electrical circuit(s) to equipment in wet areas shall be provided with five milliampere GFCI. GFCI circuits shall not be used in c-section operating rooms and delivery rooms. When GFCIs are used in critical areas, provisions shall be made to ensure that other essential equipment is not affected by activation of one interrupter.

(viii) C-section operating rooms and delivery rooms shall have general lighting in addition to that provided by special lighting units at the surgical and obstetrical tables. Each fixed special lighting unit at the operating or delivery table shall be connected to an independent circuit powered by the critical branch of the essential electrical system. Portable units may share circuits.

(ix) Indirect lighting and high-intensity lighting shall be provided in the NCCU(s). The lighting shall be able to be adjusted over individual patient care spaces. No direct ambient lighting shall be permitted in the infant care spaces, and any direct ambient lighting used outside the infant care area shall be located or framed so as to avoid any infant's direct line of sight to the fixture. This does not exclude the use of direct procedure lighting.

(x) Receptacles at each bed location in a NCCU shall be served by two branch circuits, one or more from the critical branch panel of the emergency electrical system and one or more from the normal system. One critical branch circuit shall serve only one bed location. All branch circuits from the normal system shall be from a single panelboard. All branch circuits from the emergency electrical system shall be from a single panelboard.

(xi) A minimum of seven hospital grade duplex outlets shall be conveniently located at the head of each NCCU bed, crib or bassinet. At least three of these duplex outlets shall be on the critical branch of the emergency electrical system.

(B) Nurses calling system. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(v) Outpatient suite.

(1) Architectural requirements.

(A) General. Outpatient services that the hospital provides to patients under the hospital license shall be within the hospital. Outpatient services and facilities (diagnostics, imaging, surgical, etc.) may be provided throughout the hospital within other suites, departments or units within the hospital. When an organized outpatient suite is provided for the hospital, it shall be in one identifiable contiguous location within the hospital and meet all the elements described in this subsection. To be included in the hospital license, an outpatient suite located in an office building or other building shall be physically connected to the hospital and become contiguous to the hospital. In no case may one leave the hospital, traverse the other occupancies, and then reenter the hospital to access the remaining portion of the hospital. A hospital may not occupy two or more noncontiguous areas of nonhospital occupancies, which contain intervening space of the nonhospital occupancies even if on the same floor or other floors. Outpatient facilities physically connected to the hospital with a common wall or an enclosed connection shall comply with the requirements of NFPA 101, Chapter 18.

(B) Site, administration and public areas. The following shall be provided.

(i) Parking. When an outpatient suite is provided, four parking spaces shall be required for each surgical procedure room, treatment room, and diagnostic room, plus additional spaces for each staff member.

(ii) Entrance. When an established outpatient suite in one identifiable location provides surgical services, an illuminated covered drive through entrance shall be provided.

(iii) Public waiting area. Toilet facilities, public telephone, and drinking fountain shall be provided. When pediatric services are provided, pediatric and adult patients waiting areas shall be separate.

(iv) Control station. A control station shall be located to permit staff observation of waiting area and control of access to treatment rooms, procedure rooms, diagnostic rooms, and the surgical suite.

(v) Wheelchair storage alcove. The alcove provided for wheelchair storage shall be located out of line of traffic.

(vi) Interview space. Interview spaces shall be provided for social services, credit, and admissions. Provisions shall be

made for privacy and dignity of the patient during interview, examination, and treatment.

(vii) Offices. General or individual offices shall be provided for business transaction, records, and administrative and professional staff.

(viii) Multipurpose rooms. Multipurpose rooms for conferences, meetings, and health education purposes shall be provided.

(C) Examination, treatment, and observation rooms. When examination, treatment, or observation facilities are provided, the following shall be included.

(i) Examination room. The room shall have a minimum clear floor area of 100 square feet exclusive of fixed cabinets and shelves. Each examination room shall contain a work counter, cabinets, examination light and hand washing fixture with hands-free operable controls. A clearance of three feet shall be provided at each side and the foot of the examination table.

(ii) Special purpose examination rooms. The special purpose examination room shall comply with the requirements of an examination room as described in clause (i) of this subparagraph, but room size and configuration may be modified for specialized equipment.

(iii) Treatment room. The room shall have a minimum clear floor area of 120 square feet exclusive of fixed and movable cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 10 feet. The treatment room shall contain a work counter, cabinets, medication storage, examination light and a hand washing fixture with hands-free operable controls.

(iv) Observation room. The room shall be located to permit close observation from either a nurse station or the control station. The room shall have a minimum clear area of 80 square feet exclusive of fixed and movable cabinets and shelves. Patients shall have access to a toilet room without entering the general corridor area.

(v) Multiple-bed holding/observation room/area. In a multiple-bed holding/observation room/area, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed holding/observation room/area shall contain cabinets, work counters, and a hand washing fixture with hands-free operable controls. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(D) Diagnostic facilities. Services shall be available to the outpatient suite. When separate radiology units are located within the outpatient suite, the requirements in subsection (l) of this section shall be met.

(E) Laboratory. Services shall be made available to the outpatient suite. When a separate laboratory unit is installed within the outpatient suite, the requirements in subsection (n) of this section shall be met. All laboratory services provided within the outpatient suite or by a written contractual arrangement shall comply with the requirements of §133.41(h) of this title.

(F) Surgical facilities. Outpatient surgical facilities may be provided separately or may be shared with the inpatient facilities.

(i) When a separate outpatient surgery suite is provided, it shall meet the requirements in subsection (ee) of this section.

(ii) The following additional rooms and areas shall be provided in each surgical suite wherever outpatient surgical procedures are performed. A preoperative area for outpatient use shall be provided. The area shall include a waiting room, public toilet facilities, sitting space for ambulatory patients, and at least one or more of the following: a single patient preoperative room, multiple-bed/gurney preoperative patient stations, single patient preoperative/recovery room, or multiple-bed/gurney preoperative/recovery patient stations. Traffic patterns shall be arranged for patients to enter the preoperative area from outside the surgical suite, prepare for surgical procedure and then move directly into the restricted corridor of the operating suite.

(I) When a single patient preoperative room is provided the minimum clear area is 100 square feet exclusive of aisles and fixed and moveable cabinets and shelves. The room shall contain cabinets, work counter, and a hand washing fixture with hands-free operable controls.

(II) When a multiple-bed/gurney preoperative patient station is provided, the clearance between the side of the bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed/gurney preoperative patient room shall contain cabinets, medication storage, and work counter. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. One hand washing fixture with hands-free operable controls shall be provided for every four stations or fraction thereof. Privacy shall be provided for each patient with cubicle curtains or movable screens. The requirements of this subclause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(III) When a single patient preoperative/recovery room is provided the minimum clear area is 120 square feet exclusive of aisles and fixed and moveable cabinets and shelves. The room shall contain cabinets, work counter, and hand washing fixture with hands-free operable controls.

(IV) When a multiple-bed/gurney preoperative/recovery patient station is provided, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of four feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than eight feet for single load area/room or twelve feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed/gurney preoperative/recovery patient station shall contain cabinets, medication storage, and work counter. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. One hand washing fixture with hands-free operable controls shall be provided for every four stations or fraction thereof. Privacy shall be provided for each patient with cubicle curtains or movable screens. The requirements of this subclause are illustrated in Table 8, Diagram M of §133.169(h) of this title.

(iii) A secondary recovery lounge (for outpatients requiring additional observation) with a nurse's station and a hand washing fixture with hands-free operable controls shall be provided. One hand washing fixture with hands-free operable controls shall be provided for every four secondary recovery stations or fraction thereof. In each secondary recovery station, the clearance between

a side of lounger/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of lounger/gurney shall be a minimum of six feet. The minimum distance at the foot of the lounger/gurney shall not be less than six feet for single load area/room or nine feet for double load area/room. Three feet of passage space requirement at the foot of the lounger/gurney may be shared between two loungers/gurneys. The fixed and movable cabinets and shelves shall not encroach upon the lounger/gurney clear floor space/area. Privacy shall be provided for each patient with cubicle curtains or movable screens. The requirements of this clause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(iv) A toilet room for use by outpatients shall be provided directly accessible from the outpatient preoperative, recovery and secondary recovery lounge areas. The toilet room shall contain a water closet and a hand washing fixture with hands-free operable controls. There shall be one outpatient toilet room for every ten patient stations or fraction thereof. Toilet rooms may be shared if convenient to the outpatient preoperative, recovery and secondary recovery lounge areas.

(G) Special procedure room(s). When outpatient special procedures services are provided within the outpatient suite, the special procedure room(s) shall comply with the requirements in subsection (dd) of this section.

(H) Service areas. The following service areas and facilities shall be provided within the outpatient suite unless noted otherwise.

(i) Nurse station(s). The nurse station shall contain a work counter, communication system, space for supplies, and provisions for charting.

(ii) Hand washing fixtures. Hand washing fixtures with hands-free operable controls shall be available at all patient care areas.

(iii) Patient toilet room(s). Toilet room(s) shall be conveniently located to treatment room(s), examination room(s), and diagnostic room(s) and shall include hand washing fixture(s) with hands-free operable controls.

(iv) Staff toilet facilities. Toilet rooms equipped with hand washing fixtures with hands-free operable controls shall be provided for the exclusive staff use. Toilet facilities may be provided in conjunction with the staff lounge.

(v) Staff lounge. A staff lounge with separate male and female staff clothing change rooms and toilets with hand washing fixtures with hands-free operable controls shall be provided in hospitals having a total of six or more diagnostic and treatment rooms.

(vi) Medication station. Storage and distribution of medication may be done from a medicine preparation room, medicine alcove area or from a self-contained medicine dispensing unit but must be under visual control of nursing staff. A work counter, a hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not acceptable for hand washing. The medication station may be shared with the clean workroom.

(vii) Dictation and report preparation area. This area may be accessible from the lounge.

(viii) Cast room. When a cast room is provided, it shall be equipped with hand washing facilities, plaster sink, storage, and other provisions required for cast procedures.

(ix) Wheelchair and stretcher storage. Wheelchair and stretcher storage space or alcove shall be provided and located out of direct line of traffic.

(x) Storage. Storage facilities shall be provided for office supplies, sterile supplies, pharmaceutical supplies, splints and other orthopedic supplies, and housekeeping supplies and equipment.

(xi) Ice machine. A self-dispensing ice machine shall be provided.

(xii) Clean workroom. A clean workroom or clean supply room shall be provided.

(xiii) Storage room. A storage room for the outpatient services shall be provided at least equal to 5.0% of the total area of the outpatient suite. This required storage room area may be combined with general stores.

(xiv) Soiled workroom. A soiled workroom shall be provided. It shall not have direct access to any patient treatment, examination, diagnostic rooms, or sterile rooms. The room shall contain a clinical sink or equivalent flushing rim fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and linen receptacle.

(xv) Housekeeping room. The housekeeping room shall be located within the suite. The room may be shared with an adjacent emergency suite when directly accessible from both sides.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph. Treatment rooms shall be provided with seamless flooring in accordance with requirements contained in §133.162(d)(2)(B)(iii)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph. Filtration requirements for air handling units serving the outpatient and surgical suite shall be equipped with filters having efficiencies equal to, or greater than specified for patient care areas in Table 4 of §133.169(d) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph. Sinks used for the disposal of plaster of paris shall have a plaster trap.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(w) Pediatric and adolescent nursing unit.

(1) Architectural requirements. When a facility offers pediatric care services and the nursing unit contains a total of 15 or more patient beds, cribs or bassinets, the unit shall meet the requirements contained in this subsection. Units containing less than 15 beds, cribs or bassinets, may be a part of the medical/surgical nursing unit. Each pediatric and adolescent nursing unit shall comply with the requirements contained in subsection (t)(1) of this section and the following requirements.

(A) Patient rooms. Patient rooms in a pediatric and adolescent nursing unit containing hospital beds or cribs shall comply with subsection (t)(1)(B) of this section with the following exceptions:

(i) The minimum clear floor space in a private patient room within a dedicated pediatric unit intended for a crib shall be 100 square feet exclusive of toilet room, closet, built-in cabinets, wardrobe, alcove, or vestibules. Minor encroachments including

columns and wall hung lavatories that do not interfere with functions may be ignored.

(ii) Patient rooms used for multiple cribs shall have no more than six cribs in a room. The clearance between the side of a crib and a wall/partition shall be a minimum of three feet six inches. The clearance between sides of crib shall be a minimum of six feet. The minimum distance at the foot of the crib shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the crib may be shared between two cribs. The fixed and moveable cabinets and shelves shall not encroach upon the crib clear floor space/area. One hand washing fixture with hands-free operable controls shall be provided for every three patients cribs. The requirements of this clause are illustrated in Table 8, Diagram L of §133.169(h) of this title.

(B) Airborne infection isolation suites and protective environment suites.

(i) Airborne infection isolation suites shall comply with the requirements contained in subsection (t)(1)(C) of this section and shall be located within the pediatric and adolescent nursing unit.

(ii) Protective environment suites shall comply with the requirements contained in subsection (t)(1)(D) of this section and shall be located within the pediatric and adolescent nursing unit.

(C) Pediatric nursery suite. When provided, the pediatric nursery suite shall be located in the pediatric nursing unit and shall consist of a nursery, examination/treatment room, workroom, and formula preparation room and contain the following elements.

(i) Nursery. Each pediatric nursery shall contain not more than eight bassinets. The clearance between the side of bassinet and a wall/partition shall be a minimum of three feet. The clearance between sides of bassinets shall be a minimum of six feet. The minimum distance at the foot of the bassinet shall not be less than six feet for single load area/room or nine feet for double load area/room. Four feet of the passage space at the foot of the bassinet may be shared between two bassinets. The fixed and moveable cabinets and shelves shall not encroach upon the bassinet clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram J of §133.169(h) of this title. Additional area shall be provided to accommodate workroom functions if these are located within the nursery area as specified in clauses (ii) and (iii) of this subparagraph.

(I) One hand washing fixture with hands-free operable controls shall be provided for every four patients bassinets in each pediatric nursery.

(II) Each pediatric nursery shall be provided with viewing windows for observing infants from public areas and workroom(s).

(ii) Nursery workroom. A connecting workroom shall be provided which shall contain gowning facilities at the entrance for staff, visitors, and housekeeping personnel, work space with counter, refrigerator, lavatory or sink equipped for hand washing, and storage. One workroom shall serve no more than two nurseries provided that required services are convenient to each. The workroom may be omitted if only one nursery is provided and the equivalent work area and facilities are provided within the nursery in which case the gowning facilities shall be located near the entrance to the nursery and shall be separated from the work area.

(iii) Examination/treatment room or area. An examination/treatment room or area shall be provided. The examination/treatment area may be located in a separate room or a designated part of the nursery. It shall contain a work counter, storage facilities, and a lavatory for hand washing.

(iv) On-site formula preparation. Where infant formula is prepared on the hospital site, the hospital shall provide cleanup facilities for washing and sterilizing supplies. These shall consist of a lavatory or sink equipped for hand washing, a bottle washer, work counter space, and an equipment sterilizer. A separate room for preparing infant formula shall be provided. The room shall contain a lavatory or sink equipped for hand washing, hot plate, refrigerator, work counter, formula sterilizer, and storage facilities. It may be located in the pediatric nursery or in another appropriate place within the hospital. There shall be no direct access from the formula room to a nursery.

(v) Commercially prepared formula. If a commercial infant formula is used, the storage and handling may be done in the nursery workroom or in another appropriate room elsewhere in the hospital which has a work counter, sink equipped for hand washing, and storage facilities.

(vi) Housekeeping room. A housekeeping room shall be located in the pediatric nursery suite.

(D) Service areas. The service areas in the pediatric and adolescent nursing unit shall comply with the requirements listed in subsection (t)(1)(F) of this section and the following requirements.

(i) Multipurpose or individual room(s) shall be provided for dining, educational, and play purposes. Special provision shall be made to minimize the impact noise transmission through the floor of the multipurpose room(s) to occupied spaces below. Requirements in Table 1 of §133.169(a) of this title shall be met.

(ii) Patient toilet room(s) shall be provided convenient to multipurpose room(s) and central bathing facilities.

(iii) Storage closets or cabinets for toys and educational and recreational equipment shall be provided.

(iv) Storage space shall be provided for replacement of cribs and adult beds to provide flexibility for interchange of patient accommodations.

(2) Details and finishes. Each pediatric and adolescent nursing unit shall comply with the requirements contained in subsection (t)(2) of this section.

(3) Mechanical requirements. Mechanical requirements in each pediatric and adolescent nursing unit shall comply with the requirements contained in subsection (t)(3) of this section and this paragraph.

(A) Special consideration for safety shall be given to the type of heating and cooling units, ventilation outlets, and appurtenances installed in patient areas of pediatric and adolescent nursing units.

(B) All air grilles and diffusers shall be of a type that prevents the insertion of foreign objects.

(C) All convector or HVAC enclosures exposed in the room shall be constructed with rounded corners and shall have enclosures fastened with tamper-resistant fasteners.

(4) Plumbing fixtures and piping systems. Plumbing fixtures and piping systems shall be in accordance with subsection (t)(4) of this section.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(x) Pharmacy suite.

(1) Architectural requirements.

(A) General. The pharmacy room or suite shall be located for convenient access, staff control, and security for drugs and personnel.

(B) Dispensing area. The pharmacy room or suite shall include the following functional spaces and facilities:

(i) area(s) for pickup, receiving, reviewing and recording;

(ii) extemporaneous compounding area with sufficient counter space for drug preparation and sink with hands-free operable controls;

(iii) work counter space for automated and manual dispensing activities;

(iv) storage or areas for temporary storage, exchange, and restocking of carts; and

(v) security provisions for drugs and personnel in the dispensing counter area.

(C) Manufacturing. The pharmacy room or suite shall provide the following functional spaces and facilities for the manufacturing area(s):

(i) bulk compounding area with work space and counters; and

(ii) area(s) for packaging, labeling and quality control.

(D) Storage. The following spaces shall be provided in cabinets, shelves, and/or separate rooms or closets:

(i) space for bulk storage, active storage, and refrigerated storage;

(ii) storage in a fire safety cabinet or storage room that is constructed under the requirements for protection from hazardous areas in accordance with NFPA 101, Chapter 12, for alcohol or other volatile fluids, when used;

(iii) storage in a secure vault, safe, or double locking wall cabinet for narcotics and controlled drugs; and

(iv) storage space for general supplies and equipment not in use.

(E) Intravenous (IV) solutions area. When IV solutions are prepared in a pharmacy, a sterile work area shall be provided and be in compliance with 22 TAC §291.26 (relating to Pharmacies Compounding Sterile Pharmaceuticals) and the United States Pharmacopoeia, Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

(i) The IV work area shall consist of a preparation room, hood room and, if provided, a separate chemo-hood room. Access to the preparation room shall be through the pharmacy only, access to the hood room or chemo-hood room shall be through the preparation room only.

(ii) The preparation room shall contain a work counter, gowning area and shelving.

(iii) A hand washing fixture with hands-free operable controls shall be in the preparation room and within five feet of each entrance to the hood room or chemo-hood room. Hand washing fixtures and floor drains are not allowed inside the hood room or chemo-hood room.

(iv) Laminar-flow hoods/work stations shall be located inside the hood room.

(F) Compounding aseptic isolator (CAI). When a CAI is used for compounding, in lieu of the IV solutions area, it may be done within the pharmacy provided it complies with the following.

(i) The CAI shall provide isolation from the room and maintain the International Organization for Standardization (ISO) Class 5 (100 particles greater than or equal to 0.5 microns per cubic foot) levels during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations.

(ii) The particle counts sampled shall be 6 to 12 inches upstream of the critical exposure site within the CAI and maintain ISO Class 5 levels during compounding operations.

(iii) The facility shall obtain documentation from the manufacturer that the CAI will meet this standard when located in worse than ISO Class 7 (10,000 particles greater than or equal to 0.5 microns per cubic foot environments).

(G) Administrative area(s). The following functional spaces and facilities shall be included for the administrative area(s):

(i) office area for the chief pharmacist and any other offices areas required for records, reports, accounting activities, and patients profiles;

(ii) poison control center with storage facilities for reaction data and drug information centers; and

(iii) a room or area for counseling and instruction when individual medication pick-up is available for inpatients or outpatients.

(H) Satellite pharmacy facilities. When provided, the room(s) shall include a work counter, a sink with hands-free operable controls, storage facilities, and refrigerator for medications. As applicable, items required in subparagraphs (B) and (C) of this paragraph may be incorporated into the satellite pharmacy.

(I) Service areas and facilities. The following service areas and facilities shall be provided.

(i) Hand washing facilities. A hand washing fixture with hands-free operable controls shall be located in each room where open medication is handled except for IV prepared chemo-hood rooms.

(ii) Staff facilities. Toilet rooms with hand washing fixture with hands-free operable controls may be outside the suite but shall be convenient for staff use.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Flooring in the IV solutions area for the preparation room, hood room and chemo-hood room shall be seamless and coved to the wall.

(B) IV solutions area ceiling and wall finishes for the preparation room, hood room and chemo-hood room shall be interlocking monolithic panels and sealed together or monolithic epoxy-painted gypsum board. The ceiling shall be coved to the wall.

(C) All penetrations in the walls and ceilings shall be sealed.

(D) The door from hood room shall swing into the preparation room. The door from preparation room shall swing into the chemo room. The door from preparation room shall swing into pharmacy.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) When IV solutions are prepared, the required laminar-flow system shall include a nonhygroscopic filter rated at 99.97% (HEPA). A pressure gauge shall be installed for detection of filter leaks or defects.

(B) When fume hoods are used for chemotherapy, the air/fumes shall be exhausted directly to the exterior. The hood exhaust shall not use the building exhaust system. When more than one fume hood is in the same hood room and the work stations face each other, at least six feet must separate work area openings.

(C) When fume hoods are used, the design should consider the placement and types of air distribution devices to avoid the disturbance of a uniform velocity across the face of the hood.

(D) All air entering the IV solutions area for the preparation room, hood room and chemo-hood room shall be HEPA filtered.

(E) In the IV solutions area the air pressure in the preparation room shall be positive to the pharmacy, the hood room shall be positive to the preparation room and the chemo-hood room shall be negative to the preparation room.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) Material used for plumbing fixtures shall be nonabsorptive and acid-resistant.

(B) Water spouts used at lavatories and sinks shall have clearances adequate to avoid contaminating utensils and the contents of carafes, etc.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) Under-counter receptacles and conduits shall be arranged (raised) to not interfere with cleaning of the floor below or of the equipment.

(B) Exhaust hoods shall have an indicator light indicating that the exhaust fan is in operation.

(C) Electrical circuit(s) to equipment in wet areas shall be provided with five milliampere GFCI.

(y) Radiotherapy suite. When radiotherapy services are provided, the suite may contain equipment for electron beam therapy, radiation therapy, or both. The following facilities shall be provided.

(1) Architectural requirements.

(A) Cobalt, linear accelerators, and simulation rooms require radiation protection. A medical physicist licensed under the Texas Medical Physics Practice Act, Occupations Code, Chapter 602, shall specify the type, location, and amount of radiation protection to be installed for the layout and equipment selections. Room layouts and construction shall prevent the escape of radioactive particles. Openings into the room, including doors, ductwork, vents, and electrical raceways and conduits, shall be baffled to prevent direct exposure to other areas of the facility.

(B) Cobalt, linear accelerator, and simulator rooms shall be sized in accordance with the installed equipment requirements, patient access on a stretcher, medical staff access to the equipment and patient, and access for servicing the equipment.

(C) When a mold room is provided, it shall contain a ventilation hood exhausted to the exterior and a hand washing fixture with hands-free operable controls.

(D) A block room with storage for the linear accelerator may be combined with the mold room.

(E) A hot laboratory in support of cobalt therapy shall be provided.

(F) The following service areas shall be provided unless these are accessible from other departments such as imaging or outpatient areas:

(i) a stretcher hold area adjacent to the treatment rooms, screened for privacy, and combined with a seating area for outpatients;

(ii) exam rooms for each treatment room. The rooms shall be a minimum of 100 square feet and shall be provided with hand washing facilities;

(iii) a patient gowning area with provisions for safe storage of valuables and clothing. At least one space shall be sized to allow for staff-assisted dressing;

(iv) convenient access to a housekeeping room;

(v) film file area;

(vi) film storage area for unprocessed film; and

(vii) a radioisotope decay room. This room may be combined with the hot lab.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Radiation protection shall be designed, tested and approved by a medical physicist licensed under the Texas Civil Statutes, Occupations Code, Chapter 602.

(ii) Room shielding calculations for linear accelerators, cobalt and simulation rooms shall be submitted to the Department of State Health Services' Radiation Control (RC) for approval prior to use. Shielding in diagnostic radiographic rooms will be reviewed by inspectors, in the field, subsequent to use. Any changes in design or shielding, which affects radiation exposure levels adjacent to those rooms, requires prior approval by RC.

(iii) The cobalt, simulation and linear accelerator rooms shall have ceiling heights not less than nine feet. Ceilings containing ceiling-mounted equipment shall be of sufficient height to accommodate the equipment of fixtures and their normal movement.

(iv) Properly designed rigid support structures for ceiling-mounted equipment shall be located above the finished ceiling.

(B) Finishes.

(i) Flooring in the soiled workroom and any work or treatment areas in the radiotherapy suite where radioactive materials are handled shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Walls shall be constructed of materials that are easily decontaminated from accidental radioactive spills and finished in accordance with §133.162(d)(2)(B)(iv) of this title.

(iii) Ceilings in the hot laboratory and soiled workroom shall be monolithic as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) Where fume hoods are used, the design should consider the placement and types of air distribution devices to avoid the disturbance of a uniform velocity across the face of the hood.

(B) Each hood used to process radioactive materials shall have a minimum face velocity of 90-110 feet per minute, be connected to an independent exhaust system, with suitable pressure-independent air modulating devices and alarms to alert staff of fan shutdown or loss of airflow. Each hood shall also have filters with a 99.97% efficiency (based on the dioctyl-phthalate (DOP) test method) in the exhaust stream, and be designed and equipped to permit the safe removal, disposal, and replacement of contaminated filters. Filters shall be as close to the hood as practical to minimize duct contamination.

(4) Plumbing fixtures and piping systems. Piping systems and plumbing fixtures shall comply with the requirements of §133.162(d)(4) of this title.

(5) Electrical requirements. Each radiotherapy suite shall comply with the requirements of §133.162(d)(5) of this title and this paragraph.

(A) Each radiotherapy procedure room shall have at least four electrical receptacles.

(B) Ground fault circuit interrupters shall not be used in radiotherapy procedure rooms.

(C) Nurses calling system. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(z) Rehabilitation nursing unit.

(1) Architectural requirements. When provided, each rehabilitation nursing unit shall comply with the requirements contained in subsection (t)(1) of this section and the following requirements.

(A) Accessibility requirements. All patient rooms, bathing units and toilets in each rehabilitation nursing unit and all public and common use areas shall be designed and constructed to be handicapped accessible in accordance with §133.162(d)(1)(D) of this title. These requirements shall apply in all new construction and when an existing nursing unit or a portion thereof is converted to rehabilitation nursing care from other nursing care, e.g. mental health care to rehabilitation care.

(B) Patient room suites. Patient room suites shall comply with the requirements of subsection (t)(1)(B) and the following requirements.

(i) Multi-bed patient room. The clearance between the side of a bed and a wall/partition shall be a minimum of five feet. The clearance between sides of beds shall be a minimum of four feet. The minimum distance at the foot of the bed shall not be less than four feet for single load area/room or seven feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds. The fixed and moveable cabinets and shelves shall not encroach upon the bed clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram H of §133.169(h) of this title.

(ii) Training toilet room. When a training toilet room is provided, there shall be three feet of clearance on both sides and front of the water closet fixture. The room shall be designed to comply with accessibility requirements of §133.162(d)(1)(D) of this title.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with subsection (t)(4) of this section. All plumbing fixtures shall comply with the requirements for the handicapped in accordance with §133.162(d)(1)(D) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(aa) Rehabilitation therapy suite. Rehabilitation therapy may include one or more categories of services. Where two or more rehabilitation services are provided, the services may share common areas when appropriate.

(1) Architectural requirements.

(A) Occupational therapy. When occupational therapy services are provided, the following rooms or areas shall be included:

(i) an activity area with work areas, counters and a hand washing fixture with hands-free operable controls. Work areas and counters shall be suitable for wheel chairs;

(ii) an area for teaching daily living activities with space for a bed, kitchen counter with appliances and sink, bathroom, and a table and chair. The daily living activities area may be combined with the activity area;

(iii) an office for the occupational therapist; and

(iv) a storage room for supplies and equipment.

(B) Physical therapy. When physical therapy services are provided, the following rooms or areas shall be included.

(i) Provisions shall be made for thermotherapy, diathermy, ultrasonics, and hydrotherapy when required by the functional program.

(ii) Treatment area(s) shall be provided with a minimum of 70 square feet of clear floor area for each patient station, exclusive of four foot aisle space. Privacy screens or curtains shall be provided at each treatment station.

(iii) A hand washing fixture with hands-free operable controls shall be provided in each treatment room/space. One hand washing fixture may serve up to four patient stations when cubicles or open room concepts are used and when the fixture is conveniently located.

(iv) An area shall be provided for exercise and may be combined with treatment areas in open plan concepts.

(v) An office shall be provided for the physical therapist.

(vi) Separate storage shall be provided for soiled linen, towels, and supplies.

(vii) A storage area or room for equipment, clean linen, and supplies shall be provided.

(viii) When outpatient physical therapy services are provided, the suite shall have as a minimum patient dressing areas, showers and lockers. These shall be accessible and usable by the disabled.

(C) Prosthetics and orthotics. When prosthetics and orthotics services are provided, the following rooms or areas shall be included:

(i) work space with counters and shelves for technicians;

(ii) a treatment space for evaluating and fitting with privacy screens or curtains; and

(iii) a storage area or room for equipment and supplies.

(D) Speech and hearing. When speech and hearing services are provided, the following rooms or areas shall be included:

(i) a space for evaluating and treatment with privacy screens or curtains; and

(ii) a storage area or room for equipment and supplies.

(E) Service areas. The following areas or items shall be provided in a rehabilitation therapy suite, but may be shared when multiple rehabilitation services are offered:

(i) patient waiting area(s) out of traffic with space for wheelchairs;

(ii) patient toilet facilities containing hand washing fixtures, with hands-free operable controls;

(iii) reception and control station(s). The reception and control station shall be located to provide supervision of activities areas. The control station may be combined with office and clerical spaces;

(iv) office and clerical space;

(v) wheelchair and stretcher storage room or alcove which shall be in addition to other storage requirements;

(vi) lockable closets, lockers or cabinets for securing staff personal effects;

(vii) staff toilets. The toilets may be outside the suite but shall be convenient for staff use and contain hand washing fixtures with hands-free operable controls;

(viii) soiled holding room; and

(ix) housekeeping room with service sink, conveniently accessible.

(2) Details and finishes.

(A) Details. Details shall be in accordance with §133.162(d)(2)(A) of this title.

(B) Finishes. Finishes shall be in accordance with §133.162(d)(2)(B) of this title and this paragraph.

(i) Flooring in a treatment room and soiled workroom shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Wall finishes shall be in accordance with the requirements of §133.162(d)(2)(B)(iv) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph. Air handling units serving the rehabilitation therapy suite shall be equipped with filters having efficiencies equal to, or greater than specified for patient care areas in Table 4 of §133.169(d) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(bb) Renal dialysis suite. Outpatient renal dialysis shall not be performed in the hospital's inpatient renal dialysis suite. When outpatient renal dialysis is provided within a hospital building, the service and facilities shall be separated from the hospital with a two-hour fire rated partition. The owner of the outpatient renal dialysis facility must obtain a separate license under Texas Health and Safety Code, Chapter 251, End Stage Renal Disease Facilities. Mechanical, electrical and plumbing services may be contracted from the hospital and the hospital shall maintain all rights and controls of all systems. When inpatient renal dialysis services are provided, the following rooms or areas shall be included.

(1) Architectural requirements.

(A) Dialysis services (acute). Dialysis services (acute) may be performed in critical care units and designated areas in the hospital, with appropriate equipment and space.

(B) Treatment area(s). The treatment area(s) shall be separate from the administrative area(s).

(i) Individual patient treatment room(s) shall have a minimum of 120 square feet of clear floor area exclusive of fixed and movable cabinets and shelves. The patient treatment room shall contain cabinets, work counter, and a hand washing fixture with hands-free operable controls.

(ii) In multiple-treatment stations, the clearance between the side of a station and a wall/partition shall be a minimum of three feet. The clearance between sides of stations shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-treatment stations shall contain cabinets, work counters, and hand washing fixtures with hands-free operable controls. The fixed and moveable cabinets and shelves shall not encroach upon the patient treatment station clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(iii) A nurse station shall be located within the dialysis treatment area(s) and designed to provide visual observation of all patient stations. The nurse station shall have counters for storage and access to a hand washing fixture(s) with hands-free operable controls.

(iv) Privacy shall be provided for each patient in the open treatment area with cubicle curtains or moveable screens.

(v) Storage and preparation of medication may be done from a medicine preparation room, medicine alcove or from a self-contained medicine dispensing unit and shall be under visual control of nursing staff. A work counter, a hand washing fixture that is op-

erable without the use of hands, a refrigerator, and double-locked storage for controlled substances shall be provided. (Standard cup-sinks provided in many self-contained units are not adequate for hand washing.)

(C) Home training room. When home training is provided in the unit, a private treatment area of at least 120 square feet exclusive of fixed and movable cabinets and shelves shall be provided. This room shall contain a work counter, a hand washing fixture with hands-free operable controls, and a separate drain for fluid disposal.

(D) Isolation rooms.

(i) When renal dialysis treatment is provided for persons who are known or suspected of having airborne infectious disease, these procedures shall be performed in a designated treatment room of not less than 120 square feet of floor area meeting airborne infection isolation ventilation requirements as contained in Table 3 of §133.169(c) of this title. Bathing facilities are not required.

(ii) When medical isolation for hepatitis B surface antigen (HbsAg) is provided, it shall be in a separate dedicated treatment room for a single patient with a minimum of 100 square feet clear area exclusive of fixed and movable cabinets and shelves. The treatment room shall include a work counter and a hand washing fixture with hands-free operable controls, and space for patient care supplies and equipment. The dialyzed equipment shall be designated and reserved for individual renal dialysis patients. The equipment shall be disinfected after each use. Disinfection of equipment shall occur in the treatment room.

(E) Service areas and facilities.

(i) Patient toilet(s). Patient toilet rooms shall be convenient to the treatment area(s) and include hand washing fixture(s) with hands-free operable controls.

(ii) Storage space. A storage space shall be available for wheelchairs, supply carts and stretchers. This storage shall be located out of the direct line of traffic and in addition to other storage requirements.

(iii) Water treatment room. The water treatment and equipment for the dialysis shall be located in a dedicated enclosed room.

(iv) Mixing room. Dialysis solutions may be processed from a central batch delivery system or prepared in an on-site mixing room. When provided, a mixing room shall include a work counter, sink with hands-free operable controls, storage space, and holding tanks.

(v) Dialyzers reprocessing room. When provided, the room shall be arranged for the separation and one-way movement of soiled and clean materials. This room shall include a work counter, service sink, separate hand washing fixture with hands-free operable controls, refrigerator and storage space.

(vi) Breakdown room. When provided, the room shall include a work counter, service sink, separate hand washing fixture with hands-free operable controls, and storage space. This function may be included as part of the soiled processing area of the dialyzers reprocessing room.

(vii) Nourishment station. When provided, the nourishment station shall include a work counter, a sink with hands-free operable controls, refrigerator, microwave, and storage cabinets.

(viii) Hand washing facilities. Hand washing facilities shall be provided in each examination room and treatment room. In an open multiple-treatment area one hand washing fixture shall be provided for every four treatment stations or fraction thereof.

(ix) Dictation and report preparation area. This area may be incorporated with the nurse station if adequate work space is provided.

(x) Staff facilities. Toilets may be outside the suite but shall be convenient for staff use.

(xi) Offices work area. Office space and clinical work area shall include space for records storage and report preparation.

(xii) Clean workroom. When the functional program dictates preparing patient care items, a clean workroom shall be provided and contain a work counter, a hand washing fixture with hands-free operable controls, and storage facilities for clean and sterile supplies. This function may be within the mixing room.

(xiii) Clean linen storage. There shall be a designated area for clean linen storage. This may be within a clean workroom, a mixing room, a separate closet, or an approved distribution system. If a closed cart system is used, storage of the cart shall be in an alcove.

(xiv) Soiled workroom. The soiled workroom shall contain a work counter, a clinical sink with hands-free operable controls or equivalent flushing type fixture, separate hand washing facilities, and separate waste and linen receptacles.

(xv) Housekeeping room. A housekeeping room for the exclusive use of the unit shall contain a service sink and storage for housekeeping supplies and equipment.

(2) Details and finishes.

(A) Details. Details shall be in accordance with §133.162(d)(2)(A) of this title.

(B) Finishes. Finishes shall be in accordance with §133.162(d)(2)(B) of this title and this paragraph.

(i) Flooring in a treatment room and soiled workroom shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Wall finishes shall be in accordance with the requirements of §133.162(d)(2)(B)(iv) of this title.

(iii) Ceilings in the isolation and hepatitis B rooms shall be of the monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph. Air handling units serving the renal dialysis suite shall be equipped with filters having efficiencies equal to, or greater than specified for patient care areas in Table 4 of §133.169(d) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph. The dialysis water treatment shall meet the standards as described in the American National Standard, Hemodialysis Systems, July 2003 edition, published by the American Association for the Advancement of Medical Instrumentation (AAMI), 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201, telephone (703) 525-4890.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General. Each treatment area and treatment room shall have at least two duplex electrical receptacles located on each side of a patient bed or lounge chair.

(B) Grounding. All equipment and appliances shall be properly grounded in accordance with the National Fire Protection Association 99, Standard for Health Care Facilities, §§3-3.2.1.2(a)(2) and 7-5.1, 2002 Edition (NFPA 99), published by the National Fire Protection Association. All documents published by the NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, Post Office Box 9101, Quincy, Massachusetts 02269-9101, 1-800-344-3555.

(C) Nurses calling system. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(cc) Respiratory therapy suite. The type and extent of respiratory therapy services vary greatly in each hospital. Therapy can be delivered from a large centralized area or basic services can be provided at the patient bedside.

(1) Architectural requirements.

(A) Respiratory therapy suite. When respiratory services are provided from a centralized area, the following rooms or areas shall be included:

(i) an office for the respiratory therapist;

(ii) office and clerical space with provision for filing and retrieval of patient records;

(iii) receiving/decontamination workroom with work counter or table, a deep sink, and a hand washing fixture with hands-free operable controls; and

(iv) a storage room for clean and sterile supplies which is separate from the receiving/decontamination workroom.

(v) When a blood gas analyzer is provided, it shall be located in a room and contain a counter and hand washing sink. When a portable blood gas analyzer is used, it may be used in rooms which have a work counter and hand washing facilities with hands-free operable controls. Storage of the unit may occur in an alcove or equipment storage room.

(B) Outpatient respiratory therapy services. When respiratory therapy services are provided for outpatients, the following additional areas and facilities shall be included in the centralized respiratory therapy suite:

(i) patient waiting area with space for wheelchairs;

(ii) reception and control station(s) with visual control of waiting and activities areas;

(iii) patient toilet facilities which include hand washing fixtures with hands-free operable controls;

(iv) office and clerical space; and

(v) consultation/education room.

(C) Cough-inducing and aerosol-generating procedures. All cough-inducing procedures performed on patients who may have infectious Mycobacterium tuberculosis shall be performed in rooms, booths or special enclosures using local exhaust ventilation devices with HEPA filters located at the discharge end and exhaust directly to the outside.

(D) Service areas. The following areas and facilities shall be provided for the respiratory therapy suite but may be shared with other departments when conveniently located:

(i) wheelchair and stretcher storage room or alcove which is in addition to other storage requirements;

(ii) lockable closets, lockers or cabinets for securing staff personal effects;

(iii) staff toilets which include a hand washing fixture with hands-free operable controls. Staff toilets may be located outside suite if location is near and convenient; and

(iv) housekeeping room. The housekeeping room shall be located within the suite or nearby, and shall contain a service sink and storage space for housekeeping supplies and equipment.

(2) Details and finishes.

(A) Details. Details shall be in accordance with §133.162(d)(2)(A) of this title.

(B) Finishes. Finishes shall be in accordance with §133.162(d)(2)(B) of this title and this paragraph.

(i) Flooring in a decontamination room shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Wall finishes shall be in accordance with the requirements of §133.162(d)(2)(B)(iv) of this title.

(iii) Ceilings shall be in accordance with §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(dd) Special procedure suite.

(1) Architectural requirements.

(A) General. When special procedures such as endoscopy, bronchoscopy, and cardiac catheterization and other similar special procedures are provided, procedure rooms may be in a separate suite or may be part of the surgical suite.

(i) Special procedure rooms may be incorporated in an outpatient suite.

(ii) When special procedure rooms are part of the surgical suite and noninvasive procedures are performed, these rooms are not required to be part of the sterile environment.

(iii) Nonsurgical or noninvasive procedure rooms shall have a minimum clear floor area of 250 square feet, and a minimum clear dimension between fixed cabinets and built-in shelves shall be 14 feet.

(iv) A hand washing fixture or a scrub sink with hands-free controls shall be located within five feet of the entrance to each nonsurgical procedure room either in the room or outside. Hand washing facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts and recessed out of the main traffic areas.

(v) When general anesthesia or inhalation anesthetizing agents are used during special procedures, these rooms shall

comply with the detail, finish, mechanical and electrical requirements for an operating room contained in subsection (ee) of this section.

(B) Special procedure rooms for surgical cystoscopic and other endourologic procedures.

(i) The procedure room shall have a minimum clear floor area of 350 square feet exclusive of fixed cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 15 feet.

(ii) Procedure rooms shall be designed for visual and acoustical privacy for the patient.

(iii) One scrub station shall be located within five feet of the outside entrance of each special procedure surgical room. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel, medical equipment or supply carts. The scrub sinks shall be recessed out of the main traffic areas. The scrub sink shall be located off the restricted areas of the special procedure surgical procedure rooms. Scrub sinks or sinks shall not be located inside the sterile area.

(iv) Appropriately sized areas shall be provided for male and female changing rooms within the special procedure surgical suite. These areas shall contain lockers, showers, toilets, hand washing fixtures with hands-free operable controls, and space to change into scrub suits and boots. Separate locker/changing rooms shall be provided for male and female staff. The shower and toilet room(s) may be unisex. These areas shall be arranged to provide a traffic pattern so that personnel entering from outside the special procedure surgical suite can shower, change, and move into the restricted portions of special procedure surgical suite.

(C) Catheterization laboratory. A catheterization procedure room may be in a separate suite, part of a special procedure suite, surgical suite, or in the imaging suite. The following items and facilities shall be provided.

(i) The room(s) shall be located in an area restricted to authorized personnel.

(ii) The procedure room shall be a minimum of 400 square feet of clear floor area exclusive of fixed and movable cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 18 feet.

(iii) A control room shall have a view window which permits complete observation of the patient from the control console. The control room shall be large enough to contain the efficient functioning of the X-ray and image recording equipment.

(iv) An area for viewing images and film file room shall be provided. When digital imaging is provided throughout the suite, a minimum of two X-ray film illuminators shall be provided within a central location within the catheterization laboratory and the film file room may be omitted.

(v) An equipment room large enough to contain X-ray transformers, power modules, and necessary electronics and electrical gear shall be provided.

(vi) Appropriately sized areas shall be provided for male and female changing rooms within the catheterization laboratory suite. These areas shall contain lockers, showers, toilets, hand washing fixtures with hands-free operable controls, and space to change into scrub suits and boots. Separate locker/changing rooms shall be provided for male and female staff. The shower and toilet room(s) may be unisex. These areas shall be arranged to provide a traffic pattern so that personnel entering from outside the catheterization laboratory can shower, change, and move into the restricted portions of catheterization laboratory.

(vii) One scrub station shall be located within five feet of the outside entrance of each cardiac catheterization laboratory procedure room. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel, medical equipment or supply carts. The scrub sinks shall be recessed out of the main traffic areas. The scrub sink shall be located off the restricted areas of the cardiac catheterization laboratory. Scrub sinks or sinks shall not be located inside the sterile area.

(viii) Sterilizing facilities for immediate or emergency use shall be provided unless instruments are all disposable. A work space and hand washing fixture with hands-free operable controls shall be included.

(D) Patient holding and preparation area. In suites with two or more special procedure rooms, a patient holding and preparation area shall be provided to accommodate ambulatory and stretcher patients and meet the following requirements:

(i) two-stretcher stations shall be provided for first procedure room with one additional station for each additional procedure room;

(ii) the minimum clear floor space in a private holding and preparation room shall be 100 square feet exclusive of toilet room, built-in cabinets, work counter, alcove, or vestibules. A hand washing fixture with hands-free operable controls shall be provided. A minimum of 10 feet width shall be provided for the head wall;

(iii) in a multiple-bed holding and preparation area, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram D of §133.169(h) of this title;

(iv) a control station and charting area arranged to permit staff visual observation of holding and preparation area;

(v) a work counter and a hand washing fixture with hands-free operable controls for every four beds/gurneys located in the preparation area; and

(vi) cubicle curtains at each station for patient privacy.

(E) Recovery room or area. In suites with two or more special procedure rooms, a recovery room or area shall be provided to accommodate ambulatory and stretcher patients and meet the following requirements:

(i) a minimum of one patient recovery station shall be provided for each special procedure room;

(ii) in a single patient recovery room, there shall be a minimum clear area of 130 square feet exclusive of aisles and fixed and moveable cabinets and selves. A minimum of 10 feet width shall be provided for the head wall. The room shall contain cabinets, work counter, and a hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area;

(iii) when multiple-bed/gurney recovery patient stations are provided, the clearance between side of bed/gurney and a

wall/partition shall be a minimum of four feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than eight feet for single load area/room or twelve feet for double load area/room. Four feet of passage space requirement at the foot of the bed may be shared between two beds/gurneys. The multiple-bed/gurney recovery patient station shall contain cabinets, medication storage, and work counter. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. One hand washing fixture with hands-free operable controls shall be provided for every four stations or fraction thereof. The requirements of this clause are illustrated in Table 8, Diagram M of §133.169(h) of this title;

(iv) a nurse station with a hand washing fixture with hands-free operable controls and charting area shall be provided and arranged to provide visual observation of recovery room area;

(v) a staff toilet room with a hand washing fixture with hands-free operable controls shall be provided and located within the working area to maintain staff availability to patients;

(vi) cubicle curtains shall be provided at each station for patient privacy; and

(vii) the recovery room or area may be within the patient holding area.

(F) Instrument processing room. When instruments and equipment are processed, cleaned and disinfected within the suite, dedicated rooms shall be provided. The room may serve multiple procedure rooms. The following rooms shall be included.

(i) A decontamination room shall be provided and equipped with work counters, two sinks remote from each other and a hand washing fixture with hands-free operable controls. One of the sinks shall be utility type.

(ii) A clean room shall be provided and the process of cleaning the instruments or equipment shall flow from the contaminated area to the clean area, and finally, to storage. The room shall include a work counter and a hand washing sink fixture with hands-free operable controls. Instruments and equipment shall be protected from contamination.

(iii) When endoscopy scope wash rooms are provided, cleaning, washing and drying may occur in the same room. The room shall contain two sinks.

(G) Service areas. The following services shall be provided for all types of special procedure rooms unless noted otherwise.

(i) Control station. In facilities with two or more special procedure rooms in a suite, a nurse station shall be provided and located to permit visual surveillance of all traffic which enters the special procedure rooms suite.

(ii) Dictation and report preparation area. This area may be incorporated with the control station.

(iii) Medication station. Provision shall be made for the storage and distribution of medication to be administered to patients. This may be done from a medicine preparation room, medicine alcove area or from a self-contained medicine dispensing unit. The medicine preparation room, medicine alcove area or self-contained medicine dispensing unit shall be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not acceptable for hand washing. The medication station may be shared with the clean work room.

(iv) Outpatient services. When outpatient services are provided in the special procedure suite, a separate waiting/change area shall include waiting room, dressing/gowning area, and toilet facilities and a hand washing fixture with hands-free operable controls.

(v) Patient toilet room(s). Toilet room(s) shall be conveniently located to special procedure rooms and patient changing areas and shall include hand washing fixture(s) with hands-free operable controls.

(vi) Staff toilet facilities. Facilities shall be provided for exclusive staff use and include a hand washing fixture with hands-free operable controls. The toilet may be accessible from a staff lounge, when a staff lounge is provided.

(vii) Storage. A storage room(s) shall be provided for equipment and supplies used in the special procedure suite. Each special procedure suite shall provide a minimum of 150 square feet of storage area or 50 square feet per procedure room, whichever is greater.

(viii) Wheelchair and stretcher storage. Wheelchair and stretcher storage space/alcove shall be provided and located out of direct line of traffic.

(ix) Staff storage. Storage space for employees' personal effects shall be provided.

(x) Ice machine. An ice machine shall be provided.

(xi) Clean storage room. A clean storage room shall be provided for clean supplies and linens. A hand washing fixture shall be provided with hands-free operable controls.

(xii) Soiled workroom. The soiled workroom shall not have direct connection to the special procedure or diagnostic rooms or other sterile or clean activity rooms. The room shall contain a clinical sink or equivalent flushing type fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and linen receptacle.

(xiii) Housekeeping room. A housekeeping room shall be provided for the exclusive use of the special procedure suite. It shall be directly accessible from the suite and shall contain a floor receptor or service sink and storage for supplies and housekeeping equipment.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details. Special procedure rooms shall have ceiling heights not less than nine feet.

(B) Finishes.

(i) Flooring used in special procedure rooms, decontamination room, and in the soiled workroom shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Ceiling finishes in special surgical procedure rooms and isolation rooms, soiled workroom and sterile processing rooms shall be monolithic as required by §133.162(d)(2)(B)(vi)(III) of this title.

(iii) A lay-in type ceiling is acceptable in nonsurgical special procedure rooms.

(iv) A nonsurgical or noninvasive catheterization lab shall have a washable ceiling.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) Air supply for the special procedure rooms shall be from ceiling outlets that are as near the work centers as possible. A minimum of two low return inlets shall be located diagonally opposite from one another.

(B) Return air inlets shall be not lower than four inches nor higher than 12 inches from floor level.

(C) Smoke removal systems shall be provided in accordance with §133.162(d)(3)(D)(iv)(II) of this title, for special procedure rooms that have piped-in nitrous oxide medical gas or where anesthesia is administered to patients.

(D) The decontamination room shall meet the ventilation requirements that are contained in Table 3 of §133.169(c) of this title.

(E) Each special procedure room and recovery room shall have wall-mounted temperature and humidity indicating devices.

(F) When patients with airborne infectious disease are treated, the room shall meet requirements for airborne infection ventilation for patient care areas in accordance with Table 3 of §133.169(c) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) Drainage and waste piping shall not be installed within the ceiling or installed in an exposed location in special procedure rooms and sterile processing rooms unless precautions are taken to protect the space below from leakage and condensation from necessary overhead piping. Any required secondary protection shall be labeled, "code required secondary drain system" every 20 feet in a highly visible print or label.

(B) A medical gas system shall be provided in accordance with §133.162(d)(4)(A)(iii) and (iv) and Table 6 of §133.169(f) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) X-ray film illuminators for handling at least four films simultaneously shall be provided in a central location. When the entire special procedure suite is provided with digital imaging system capabilities, a minimum of two X-ray film illuminators viewers shall be provided.

(ii) Each special procedure room shall have at least six duplex electrical hospital grade receptacles.

(iii) In locations where mobile X-ray, laser, or other equipment requiring special electrical configuration is used, the additional receptacles shall be distinctively marked for the special use.

(iv) The electrical circuit(s) to equipment in wet areas shall be provided with GFCIs. GFCI circuits shall not be used in special procedure rooms. When ground fault circuit interrupters are used in critical areas, provisions shall be made to ensure that other essential equipment is not affected by activation of one interrupter.

(v) Special grounding system in areas such as special procedure rooms where a patient may be treated with an internal probe or catheter the ground system shall comply with Chapter 10, NFPA 99 and Article 517, NFPA 70.

(vi) Special procedures rooms shall have general lighting in addition to that provided by special lighting units at the procedure tables.

(B) Nurses calling system. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(ee) Surgical suite.

(1) Architectural requirements.

(A) General.

(i) A public waiting room shall be provided.

(ii) Toilet facilities, public telephone(s), and drinking fountain(s) shall be provided within or nearby.

(iii) The surgical suite shall be located and arranged to preclude unrelated traffic through the suite.

(iv) When outpatient surgery is provided within the surgical suite additional requirements in subsection (v)(1)(F) of this section shall be provided.

(B) General operating room(s). A minimum of one operating room shall be provided and shall have a minimum clear floor area of 400 square feet exclusive of fixed and movable cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 20 feet. There shall be no direct access between operating rooms.

(C) Operating rooms for cardiovascular, orthopedic, neurological, and other special surgical procedures that require additional personnel and large equipment.

(i) When provided, these rooms shall have a minimum clear floor area of 600 square feet, with a minimum of 20 feet clear dimension exclusive of fixed or wall-mounted cabinets and built-in shelves.

(ii) An additional room shall be provided in the restricted area of the surgical suite, preferably adjoining this operating room, where extra corporeal pump(s), supplies and accessories can be stored and serviced.

(iii) When complex orthopedic surgery and neurosurgery are performed, additional rooms shall be provided in the restricted area of the surgical suite, preferably adjoining the specialty operating rooms, for storage of equipment used during these procedures.

(D) Preoperative patient holding area(s) or room(s). In facilities with two or more operating rooms, a patient holding area or rooms shall be provided. The preoperative patient holding area may be used for secondary recovery. The area shall meet the following requirements.

(i) The minimum clear floor space in a private preoperative holding room shall be 100 square feet exclusive of aisles and fixed and moveable cabinets and selves. A minimum of nine feet width shall be provided for the head wall.

(ii) In a multiple-bed preoperative holding area, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The fixed and moveable cabinets and shelves shall not encroach upon the

bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(iii) A control station and charting area shall be provided and arranged to permit staff visual observation of holding and preparation area.

(iv) A work counter with hand washing fixture with hands-free operable controls shall be provided and located in the preparation area.

(v) Cubicle curtains shall be provided at each station for patient privacy.

(vi) One hand washing fixture with hands-free operable controls shall be provided for every four preoperative holding beds or fraction thereof. Fixtures shall be uniformly distributed. One hand washing fixture with hands-free operable controls shall be provided within each single-bed preoperative holding room.

(E) Post-anesthesia care units.

(i) Post-anesthesia care units (PACU) for surgical patients shall contain a medication distribution station, nurse station with charting facilities, clinical sink provisions for bedpan cleaning, and storage space for stretchers, supplies and equipment. The nurse station shall be arranged to permit the staff to have full visual control of the PACU area.

(ii) A minimum of one and a half patient stations per operating room shall be provided for post-anesthesia care or fraction thereof. A minimum of two stations shall be provided when there is only one operating room.

(iii) The minimum clear floor space in a private recovery room shall be 130 square feet exclusive of aisles and fixed and moveable cabinets and selves. A minimum of 10 feet width shall be provided for the head wall. The room shall contain cabinets, work counter, and hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area.

(iv) In multiple-bed/gurney recovery patient stations, the clearance between the side of bed/gurney and a wall/partition shall be a minimum of five feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than eight feet for single load area/room or twelve feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multi-bed/gurney recovery patient station shall contain cabinets, medication storage, and work counter. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram N of §133.169(h) of this title.

(v) Special provisions shall be made to keep medical isolation infectious patients separate during surgical recovery. An isolation room meeting the requirements in subsection (t)(1)(C) of this section may meet this requirement if conveniently located near the surgical suite and otherwise complies with requirements for a PACU except that a patient toilet room is not required. The recovery isolation room shall have a minimum clear floor area of 120 square feet. In addition, the recovery isolation room medical gas system outlet requirements shall be in accordance with Table 6 of §133.169(f) of this title for recovery room(s).

(vi) Cubicle curtains shall be provided for patient privacy.

(vii) At least one door to the PACU room shall be within the surgical suite.

(viii) Staff toilet facilities and a hand washing fixture with hands-free operable controls shall be located within or immediately adjacent to the PACU.

(ix) One hand washing fixture shall be provided for every four recovery beds or fraction thereof in open wards. Fixtures shall be uniformly distributed. One hand washing fixture shall be provided within each single-bed recovery room.

(F) Separation of recovery patients. Provisions shall be made for separating all patients subject to general anesthesia from those who did not receive general anesthesia. This requirement may be satisfied by providing separate recovery rooms, cubicles, secondary recovery rooms or scheduling of procedures.

(G) Service areas. Services, except for the enclosed soiled workroom and the housekeeping room, may be shared with the obstetrical facilities if the functional program reflects this concept. Service areas, when shared with delivery rooms, shall be designed to avoid the passing of patients or staff between the operating room and the delivery room areas.

(i) Control station. A control station located to permit visual surveillance of all traffic entering the surgical suite shall be provided.

(ii) Office. A supervisor's office or station shall be provided.

(iii) Scrub facilities. Two scrub stations shall be located in the restricted corridor within five feet of the entrance of each operating room. Two scrub stations may serve two operating rooms if the scrub stations are located adjacent to the entrance of both operating rooms. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel, medical equipment, or supply carts. Viewing panels shall be provided for observation of the surgical room interior. The scrub sinks shall be recessed out of the main traffic areas. The alcove shall be located within the restricted areas of the surgical suite. Scrub sinks shall not be located inside the sterile area.

(iv) Substerile facilities. Sterilizing facilities located conveniently to the operating rooms for immediate or emergency use with work counter shall be provided.

(v) Anesthesia workroom. The anesthesia workroom shall contain a work counter, sink with hands-free operable controls and storage space for medical gas cylinders and other anesthesia equipment.

(vi) Medication station. Storage and distribution of medication may be done from a medicine preparation room, medicine alcove area or from a self-contained medicine dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not acceptable for hand washing. The medication station may be shared with the clean work room.

(vii) General storage room(s). A minimum of 50 square feet per operating room is required for general storage space(s). The minimum requirement for three operating rooms or less is 150 square feet. This storage room is exclusive of soiled holding, sterile supplies, clean storage, drug storage, locker rooms and storage alcoves.

(viii) Orthopedic surgery storage. Splints and traction equipment shall be stored in an enclosed storage room. Storage shall be outside the operating room but must be conveniently located.

(ix) Storage alcove. An alcove(s) located out of the direct line of traffic shall be provided for the storage of stretchers, portable X-ray equipment, fracture tables, warming devices, auxiliary lamps, etc.

(x) Surgical suite staff clothing change rooms. Appropriately sized areas shall be provided for male and female personnel working within the surgical suite. These areas shall contain lockers, showers, toilets, hand washing fixtures with hands-free operable controls, and space to change into scrub suits and boots. Separate locker/changing rooms shall be provided for male and female staff. The shower and toilet room(s) may be unisex. These areas shall be arranged to provide a traffic pattern so that personnel entering from outside the surgical suite can shower, change, and move directly into the restricted areas of the surgical suite.

(xi) Lounge. A lounge shall be provided in hospitals with three or more operating rooms. The lounge shall permit staff use without leaving the surgical suite and may be accessed from the clothing changing rooms. The lounge shall not have direct access from outside the surgical suite. When the lounge is remote from the clothing change rooms, toilet facilities and a hand washing fixture with hands-free operable controls accessible from the lounge shall be provided.

(xii) Staff toilet facilities. Toilet facilities located in the surgical suite for exclusive staff use shall be provided and contain a hand washing fixture with hands-free operable controls. The toilet room may be accessible from a staff lounge, when provided.

(xiii) Dictation and report preparation area. This may be accessible from the lounge area.

(xiv) Cast room. When a cast room is provided it shall be equipped with hand washing facilities, plaster sink, storage, and other provisions required for cast procedures. This room may be located in the emergency room.

(xv) Ice machines. An ice machine shall be provided for therapeutic purposes. A self-dispensing ice machine shall be provided for human consumption.

(xvi) Clean workroom or clean supply room. A clean workroom is required when clean materials are assembled within the surgical suite prior to use or following the decontamination cycle. It shall contain a work counter, a hand washing fixture with hands-free operable controls, storage facilities for clean supplies, and a space to package reusable items. The storage for sterile supplies must be in a separate room. When the room is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and hand washing fixture may be omitted.

(xvii) Sterile core. When a surgical suite contains a sterile core, it shall be free of any cross-traffic of staff and supplies from the soiled/decontaminated areas to the sterile/clean areas. The use of facilities outside the operating room for soiled/decontaminated processing, clean assembly and sterile processing shall be designed to move the flow of goods and personnel from dirty to clean without compromising universal precautions or aseptic techniques in both departments.

(xviii) Soiled workroom. The soiled workroom shall contain a clinical sink or equivalent flushing type fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and linen receptacle. The clinical sink and work counter may be eliminated if the room is used only for temporary holding of soiled material and cleaning of equipment/instruments and sterilization is provided outside the surgical suite. Provisions shall be made for the disposal of liquid waste. The soiled workroom shall be provided for the exclusive use of the surgical suite, shall be located in the restricted area of the surgical suite, and shall not have direct connection with operating rooms, delivery rooms or other sterile activity rooms.

(xix) Housekeeping room. A housekeeping room containing a floor receptor or service sink and storage space for housekeeping supplies and equipment shall be provided for the exclusive use of the surgical suite and shall be directly accessible from the surgical suite.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Operating rooms shall have ceiling heights not less than nine feet.

(ii) Recreation rooms, exercise rooms, equipment rooms, and similar spaces where impact noises may be generated shall not be located directly over operating suites, unless special provisions are made to minimize such noise.

(B) Finishes.

(i) Flooring within operating rooms, soiled workrooms and sterile processing rooms shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Walls in operating rooms, special procedures rooms, and soiled workrooms shall comply with the requirements of §133.162(d)(2)(B)(iv)(II)of this title.

(iii) Ceilings in operating rooms, isolation rooms, soiled workroom and sterile processing rooms shall be monolithic as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) Air supply for the operating rooms shall be from ceiling outlets near the center of the work area to efficiently control air movement. A minimum of two return air inlets located diagonally opposite from one another and near floor level shall be provided. Design should consider turbulence and other factors of air movement to minimize airborne particulate matter. Where extraordinary procedures require special designs, the installation shall be reviewed on a case by case basis.

(B) Smoke removal systems shall be provided in accordance with §133.162(d)(3)(D)(iv)(II) of this title.

(C) The ventilation system for anesthesia storage rooms and medical gases storage shall conform to the requirements of Chapter 5, NFPA 99, §5.1.3.3.3.

(D) Each operating room, PACU, and recovery room shall be provided with conveniently mounted temperature and humidity indicating devices.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) General.

(i) Drainage and waste piping shall not be installed above or below ceilings in operating rooms, and sterile processing

rooms unless precautions are taken to protect the space below from leakage and condensation from necessary overhead piping. Any required secondary protection shall be labeled, "code required secondary drain system" every 20 feet in a highly visible print or label.

(ii) Floor drains shall not be installed in operating rooms. Flushing rim type floor drains may be installed in cystoscopic operating rooms. If a floor drain is installed in cystoscopy, it shall contain a nonsplash, horizontal-flow flushing bowl beneath the drain plate.

(iii) Sinks used for the disposal of plaster of paris shall have plaster trap.

(B) Medical gas systems. Medical gas systems and outlets shall be provided in accordance with §133.162(d)(4)(A)(iii) and Table 6 of §133.169(f) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) X-ray film illuminators for handling at least four films simultaneously shall be provided in each operating room. When the entire surgical suite is provided with digital imaging system capabilities, a minimum of two X-ray film illuminator viewers shall be provided. The film illuminators shall be mounted within the central area of the suite.

(ii) Each operating room shall have at least eight duplex electrical hospital grade receptacles of which three shall be located convenient to the head of the procedure table. Each PACU recovery station shall have a minimum of seven receptacles at the head of each bed.

(iii) Special grounding system for critical care areas such as operating rooms, and special procedure rooms where patients are subjected to invasive procedures and connected to line-operated, electromedical devices shall comply with NFPA 99, Chapter 9, and NFPA 70, Article 517.

(iv) Operating rooms and special procedure rooms shall have general lighting in addition to that provided by special lighting units at the surgical tables. Each fixed special lighting unit at the operating or delivery table shall be connected to an independent circuit powered by the critical branch of the essential electrical system. Portable units may share circuits. At least one general lighting fixture shall be served from a normal branch panel.

(v) Operating rooms shall be provided with one or more battery-powered emergency lighting units as required by NFPA 99, §13.4.1.2.6(E).

(vi) Operating rooms shall be provided with at least one receptacle powered from a normal power panel. Receptacle shall be labeled, "Normal power receptacle, use only in the event of loss of critical system."

(B) Nurses calling system. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(ff) Universal care suite.

(1) Architectural requirements. Architectural requirements shall be in accordance with §133.162(d)(1) of this title and this paragraph.

(A) General. When a universal care suite is provided, the universal care suite shall be a separate suite(s) operated separately from other suites in the hospital.

(i) All universal care suite patient rooms shall be single patient rooms and have a minimum clear floor area of 200 square feet per bed exclusive of anterooms, vestibules, toilet rooms, closets, lockers, wardrobes, and/or alcoves. A minimum of 13 feet width shall be provided for the head wall.

(ii) Minor encroachments including columns and wall hung lavatories that do not interfere with functions may be ignored when determining space requirements for patient rooms. Required clear floor space for patient rooms shall be exclusive of toilet rooms, closets, lockers, built-in cabinets, wardrobes, alcoves, or vestibules.

(iii) Each universal care suite patient room shall be located on an exterior wall and shall have a window. Windows shall be in accordance with subsection (t)(2)(A)(iv) and (v) of this section.

(iv) Each universal care suite patient room shall have access to a bathroom without having to enter the general corridor area. Each bathroom shall contain a toilet, a hand washing fixture with hands-free operable controls and bathing facilities, and storage shelf or cabinet.

(v) A hand washing fixture with hands-free operable controls shall be located in each patient room near the entrance of the room and in the patient bathroom.

(vi) A minimum of one airborne infection isolation room and patient bathroom shall be provided in accordance with subsection (t)(1)(C)(iii), (iv) and (v) of this section. The universal care suite infection isolation room shall have a minimum clear floor area of 200 square feet per bed exclusive of anterooms, vestibules, toilet rooms, closets, lockers, wardrobes, and/or alcoves. A minimum of 13 feet width shall be provided for the head wall. The universal care suite isolation patient room shall have a bathroom without having to enter the general corridor area. Each bathroom shall contain a toilet, a hand washing fixture with hands-free operable controls and bathing facilities, and storage shelf or cabinet.

(vii) Viewing panels in the door or walls of these rooms are required. Curtains or other means shall be provided to cover the viewing panels when visual privacy is required.

(viii) Each patient shall have a wardrobe, locker, or closet that is suitable for hanging full-length garments and for storing personal effects. A minimum of 12 lineal inches of hanging space shall be provided per patient.

(ix) Each universal care room shall be provided with X-ray film illuminators for handling at least two films simultaneously. When the entire universal care suite is provided with digital imaging system capabilities, a minimum of two X-ray film illuminator viewers shall be provided. The film illuminators shall be mounted within the central area of the suite.

(B) Pediatrics. When a universal care suite is provided for pediatrics, the suite shall comply with the requirements contained in this paragraph and the following.

(i) A sleeping space shall be provided for parents who spend long hours with the patient. This space may be within the patient room or separate from the patient area but shall be in communication with the universal care suite staff.

(ii) A room shall be provided for private consultation and shall be located within, or convenient to, the universal care suite. The multipurpose room noted in subparagraph (D)(iv) of this paragraph will meet this requirement if conveniently located.

(iii) Storage space for infant formula shall be provided. This functional space may be outside the universal care suite but shall be available for use at all times.

(iv) Storage cabinets or closets for toys and games shall be provided within the room.

(v) Storage closet for cots, bed linens, and other items needed for overnight accommodation of parents shall be provided in the general location of sleeping accommodations.

(C) Universal care suite services and facilities. The following services and facilities shall be provided.

(i) A visitors' waiting space shall be provided with toilet facility(ies), public telephone(s), and drinking fountain(s). One waiting space may serve other units.

(ii) The nurse station shall be located to permit direct visual observation of each patient served. Video cameras or mirrors shall not be substituted for direct visual observation. The nurse station shall have space for counters and storage. The counter height shall not exceed 42 inches. The nurse station may be combined with or include centers for reception and communication.

(iii) When individual nurse substations are provided and located at each patient room(s), they shall be located to permit direct visual observation of each patient served. The nurse substation shall have space for counter, storage space and a recessed sitting space. The substation shall be at a minimum recessed from the egress corridor one foot six inches.

(iv) Charting and dictation area(s) for physicians for recording, record storage and reviews shall be provided. Dictation space may be in a separate room or alcove. Suitable space shall be provided when computers are used for the clinical records.

(v) Storage space shall be provided for emergency equipment in the unit.

(vi) Storage and distribution of medication may be done from a medicine preparation room, medicine alcove area or from a self-contained medicine dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not acceptable for hand washing. The medication station may be located with the clean work room.

(vii) A soiled workroom shall be provided and contain a clinical sink or equivalent flushing rim type fixture with hot and cold mixing faucet, separate hand washing facilities with hands-free operable controls, and separate waste and soiled linen receptacles.

(viii) A soiled holding room may be provided when all the universal care suite patient toilet rooms have bedpan washers. The soiled holding room shall contain a hand washing fixture with hands-free operable controls and separate waste and soiled linen receptacles.

(ix) A clean workroom or clean supply room shall be provided. A clean workroom when used for preparing patient care items shall contain a work counter, hand washing facilities, and storage facilities for clean and sterile supplies. When a clean supply room is used only for storage and holding as part of a distribution system of clean and sterile supplies, the work counter and hand washing facilities may be omitted.

(x) A nourishment station shall contain a work counter, a sink with hands-free operable controls, refrigerator, cabinets, and not be located in the medication room or the clean workroom. Space shall be included for temporary holding of unused or soiled dietary trays.

(xi) An ice machine shall be provided for ice for treatment and patient use. Ice-making equipment for treatment may be in the clean workroom or the nourishment station.

(xii) An intravenous solution support shall be provided at each patient bed. The intravenous solution shall not be suspended directly over the patient.

(xiii) The stretcher storage alcove provided for stretcher or bassinet storage shall be located out of direct line of traffic.

(xiv) Securable closets or cabinet compartments for the personal effects of nursing personnel, located in or near the nurse station, shall be provided. At a minimum, these shall be large enough for purses and billfolds. Coats may be stored in closets or cabinets on each floor or in a central staff locker area.

(xv) Twenty square feet of equipment storage shall be provided for each patient station. These storage areas shall be out of the way of the corridor traffic.

(xvi) A housekeeping room shall be provided and contain a service sink, storage for housekeeping supplies, and equipment. A shared nursing unit housekeeping room that is adjacent to the universal care suite is acceptable.

(D) Other required areas/rooms. The following areas/rooms shall be provided and may be located outside the unit if conveniently accessible.

(i) Offices. Room(s) shall be provided for the universal care suite medical staff, nursing management and administrative personnel. The offices shall be large enough to permit consulting with members of the universal care suite staff and visitors. The offices shall be linked with the unit by telephone or an intercommunications system.

(ii) Staff lounge. A staff lounge shall include toilet facilities with a hand washing fixture with hands-free operable controls. The lounge(s) shall be located so that staff may be recalled quickly to the patient area in emergencies. One lounge may serve multiple units when the lounge is adjacent to the units.

(iii) On-call rooms. Physicians and other staff on 24-hour on-call work schedules shall be provided with sleeping rooms with access to a shower(s), toilet(s), and lavatory(ies). If an on-call room(s) is not within the universal care suite served, a dedicated telephone or intercom system shall connect the on-call room(s) to the universal care suite.

(iv) Multipurpose room(s). A multipurpose room shall be provided for patient conferences, reports, education, training sessions, and consultation. This room(s) must be accessible to the universal care suite.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) At least one door to a universal care suite room shall be not less than four feet wide and arranged to minimize interference with movement of beds and large equipment.

(ii) Sliding doors in the universal care suite shall not have floor tracks and shall have hardware that minimizes jamming possibilities, in accordance with §133.162(d)(2)(A)(vi) of this title.

(iii) Glazing in viewing panels shall be safety glass, wire glass, or clear plastic.

(iv) Recreation rooms, exercise rooms, equipment rooms, and similar spaces where impact noises may be generated shall not be located directly over the universal care suite, unless special provisions are made to minimize such noise.

(v) Each patient shall have access to a telephone directly from each bed. The telephone may be omitted at a pediatric universal care suite bed.

(B) Finishes.

(i) Flooring used in universal care suite patient rooms, patient toilet rooms, and soiled workrooms shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Ceilings in the soiled workroom shall be monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph. Room recirculating units shall not be used.

(A) Outside air shall be supplied to each patient room by a central air handling unit to provide make-up air for air exhausted from the bathroom in accordance with Note 3, Table 3 of §133.169(c) of this title.

(B) Each patient room bathroom shall be exhausted continuously to the exterior in accordance with Table 3 of §133.169(c) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) Receptacles at each bed location in a universal care suite shall be served by two branch circuits, one or more from the critical branch panel of the emergency electrical system and one or more from the normal system. One critical branch circuit shall serve only one bed location. All branch circuits from the normal system shall be from a single panelboard. All branch circuits from the emergency electrical system shall be from a single panelboard.

(ii) A minimum of seven hospital grade duplex outlets shall be conveniently located at the head of each bed. At least three of these duplex outlets shall be on the critical branch of the emergency electrical system.

(iii) One duplex receptacle connected to a normal branch circuit and one duplex outlet connected to the critical branch circuit shall be located on opposite sides of the head of each bed. In addition at least one duplex outlet shall be located on each wall. A dedicated outlet shall be provided at the television location.

(iv) Hospital grade receptacles in the pediatric universal care suite shall be tamper-resistant or provided with GFCIs.

(B) Illumination requirements.

(i) Each single patient room and multi-patient wards shall be provided with general lighting and night lighting. General lighting and night lighting shall be controlled at the room entrance. All controls for lighting in patient areas shall be of the quiet operating type. Control of night lighting circuits may be achieved by automatic means and in such instances control of night lighting at the room entrance shall not be required. At least one general light fixture and night lighting shall be powered from the critical branch of the essential electrical system.

(ii) A reading light shall be provided over each patient bed. Reading light control shall be readily accessible from each patient bed. Flexible light arms, if used, shall be mechanically controlled to prevent the bulb from coming in contact with bed linen. High heat-producing light sources such as incandescent and halogen shall be avoided to prevent burns to patients and/or bed linen. Light sources shall be covered with a diffuser or a lens.

(iii) A wall or ceiling-mounted lighting fixture shall be provided above each lavatory.

(iv) A ceiling-mounted fixture shall be provided in patient bathrooms where the lighting fixture above the lavatory does not provide adequate illumination of the entire bathroom. Some form of fixed illumination shall be powered from the critical branch.

(C) Nurses calling systems. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

§133.166. Mobile, Transportable, and Relocatable Units.

(a) Definitions.

(1) Mobile unit--Any pre-manufactured structure, trailer, or self-propelled unit equipped with a chassis on wheels and intended to provide shared medical services to the community on a temporary basis. Some of these units are equipped with expanding walls and designed to be moved on a daily basis.

(2) Relocatable unit--Any structure, not on wheels, that is built to be relocated at any time and provide medical services. These structures vary in size.

(3) Transportable unit--Any pre-manufactured structure or trailer, equipped with a chassis on wheels, intended to provide shared medical services to the community on an extended temporary basis. These units are designed to be moved periodically, depending on need.

(b) General. When mobile, transportable and relocatable units are utilized to provide patient treatment services on the hospital premises, these units shall be treated as buildings and constructed to the required occupancy as follows.

(1) When such units are provided for diagnostic, treatment or procedural services to patients who are litter borne, under general anesthesia, or incapable of self-preservation, the unit shall be constructed in accordance with Chapter 18 of the National Fire Protection Association 101, Life Safety Code, 2003 edition (NFPA 101), relating to health care occupancy, published by the National Fire Protection Association. All documents published by the NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address and telephone number: Post Office Box 9101, 1 Batterymarch Park, Quincy, Massachusetts 02269-9101, (800) 344-3555.

(2) When such units provide diagnostic, treatment, or procedural services to patients who are not litter borne, not under general anesthesia, and are capable of self-preservation, the unit may be constructed in accordance with Chapter 38 of NFPA 101 (relating to Business Occupancy).

(c) Common elements.

(1) Site requirements.

(A) Sites shall have a level concrete or asphalt pad and be designed for the structural loads of the unit.

(B) The sites shall provide hazard-free drop-off zones and adequate parking for patients. The site and location of the unit shall not restrict access for fire or emergency vehicles.

(C) Each site shall provide access to the unit for the handicapped, and wheelchair and stretcher patients.

(D) When a mobile, transportable, or relocatable unit is not physically attached to the hospital and provides inpatient services, a covered walkway or enclosure from the hospital to the unit shall be provided to ensure patient safety from the outside elements.

(E) The location of the unit shall be such that engine exhaust fumes from the unit are kept away from any fresh air intake of the hospital.

(F) When a mobile, transportable, or relocatable unit is permanently connected appropriately for the climate to the hospital or the unit does not move on a regular basis, i.e. every 90 days or less, the units shall be provided with the following equipment and systems connected to the hospital:

(i) fire alarm system;

(ii) sprinkler system;

(iii) electrical system and the essential electrical system;

(iv) water and waste water system;

(v) medical gas systems; and

(vi) nurses calling systems.

(2) Support services. Support services shall meet the requirements of this chapter for new construction. These support services and areas shall be provided either within the mobile, transportable, or relocatable unit or located within the hospital adjacent to the unit served.

(3) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title (relating to New Construction Requirements).

(4) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(5) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(6) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

§133.167. Preparation, Submittal, Review and Approval of Plans, and Retention of Records.

(a) General.

(1) Hospital owners/operators may not begin construction of a new building, additions to or renovations or conversions of existing buildings until the department approves final construction documents.

(2) Plans and specifications describing the construction of new buildings and additions to or renovations and conversions of existing buildings shall be prepared by registered architects and/or licensed professional engineers and meet the requirements of this subchapter.

(3) The names of spaces used in the functional program narrative, preliminary documents, final construction documents and specifications shall be consistent with the names of the spaces used in this chapter.

(4) The department shall notify the hospital owner/operator of the result of its review of each type of submission discussed in this section.

(5) The hospital owner/operator shall respond to all department requests for additional information, including providing a plan of correction for deficiencies cited by the department.

(6) Once final construction documents are approved, the hospital owner/operator shall request inspections in accordance with §133.168 of this title (relating to Construction, Inspections, and Approval of Project).

(7) When construction is delayed for longer than one year from the plan approval or self-certification approval date, construction documents shall be resubmitted to the department for review and approval. The plans shall be accompanied by a new Application for Plan Review, plan review fee, and functional program narrative.

(8) The hospital owner/operator shall provide written notification to the department when a project has been placed on hold, canceled or abandoned.

(9) The department may close a project file after one year of assigning an application number to a project if the project has been placed on hold. Plan review fees are nonrefundable.

(b) Submission of projects and assignment of application number.

(1) The hospital owner/operator or representative shall submit the following items to the department in care of the mailing or overnight delivery address that appears on the Application for Plan Review:

(A) a completed and signed Application for Plan Review. The Application for Plan Review may be obtained by calling the department's Architectural Review Group, telephone (512) 834-6649;

(B) the applicable plan review fee in accordance with §133.26 of this title (relating to Fees);

(C) a functional program narrative in accordance with subsection (d) of this section; and

(D) final construction documents in accordance with subsection (f) of this section.

(2) The cost of submitting documents/plans and specifications shall be borne by the sender.

(3) Once the department has determined that the submission required in paragraph (1) of this subsection is complete, the department will assign an application number to the project that must be referenced on all documents and correspondence related to the project. Final construction documents will be reviewed in the chronological order received.

(4) All deficiencies noted in the final plan review shall be satisfactorily resolved before approval of project for construction will be granted.

(5) Construction shall not begin until the hospital owner/operator of the facility receives written notification from the department that the final construction documents have been approved.

(c) Feasibility conference. A hospital owner/operator or representative may request a feasibility conference. A feasibility conference is an informal meeting between a member of the department's Architectural Review Group staff and the hospital owner/operator or representative to determine the feasibility of a project, for consultation

and informational purposes, and to facilitate and establish understanding of compliance with the rules and codes.

(1) A feasibility conference is not a substitute for plan review.

(2) A hospital owner/operator or representative may schedule a feasibility conference by calling the department's Architectural Review Group, telephone number (512) 834-6649.

(3) The hospital owner/operator or representative shall provide at the feasibility conference the items in subsection (b)(1)(A) - (C) of this section and a set of preliminary plans or final construction documents.

(4) The hospital owner/operator or representative is responsible for recording conference notes and shall submit the notes to the department.

(d) Functional program narrative. The hospital owner/operator shall submit a functional program narrative to the department with each new project in accordance with subsection (b)(1)(C) of this section. The functional program narrative shall be presented on facility letterhead, signed by hospital administration, include the functional description of each space, and the following:

(1) departmental relationships, number of patient beds in each category, and other basic information relating to the fulfillment of the facility's objectives;

(2) a description of each function to be performed, approximate space needed for these functions, occupants of the various spaces, projected occupant load, types of equipment required, interrelationship of various functions and spaces, and any special design features;

(3) energy conservation measures, included in building, mechanical and electrical designs;

(4) a description of the type of asepsis control in diagnostic and treatment areas; and

(5) the type of construction (existing or proposed) as stated in Table 18.1.6.2 of National Fire Protection Association 101, Life Safety Code, 2003 edition (NFPA 101), published by the National Fire Protection Association. All documents published by the NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address and telephone number: Post Office Box 9101, 1 Batterymarch Park, Quincy, Massachusetts 02269-9101, (800) 344-3555.

(e) Preliminary documents. The department may request preliminary documents. If requested by the department, the submission shall consist of the items in subsection (b)(1)(A) - (C) of this section, preliminary plans, and outline specifications. The documents shall contain sufficient information to establish the project scope, description of functions to be performed, project location, required fire safety and exiting requirements, building construction type, compartmentation showing fire and smoke barriers, bed count and services, and the usage of all spaces, areas, and rooms on every floor level.

(f) Final construction documents. Final construction documents and specifications shall be submitted to the department for review and approval prior to start of construction. All final documents and specifications shall be appropriately sealed and signed by the project registered architect and professional engineer(s) licensed by the state of Texas.

(1) Submission of final construction documents. The hospital owner/operator shall submit to the department for review and approval the items in subsection (b)(1)(A) - (C) of this section (if not previously submitted with preliminary documents) and one set of final construction documents and specifications covering the construction of new buildings or alterations, additions, conversions, modernizations, or renovations to existing buildings.

(2) Preparation of final construction documents. Construction documents shall be well-prepared so that clear and distinct prints may be obtained, shall be accurately and adequately dimensioned, and shall include all necessary explanatory notes, schedules, and legends and shall be adequate for contract purposes. Compliance with model building codes and this chapter shall be indicated. The type of construction, as classified by National Fire Protection Association 220, Standard on Types of Building Construction, 1999 edition, shall be provided for existing and new facilities. Final plans shall be drawn to a sufficiently large-scale to clearly illustrate the proposed design but not less than one-eighth inch equals one foot. All spaces shall be identified by usage (using the names of spaces used in this chapter) on all plans (architectural, fire safety, mechanical, electrical, etc.) submitted. Separate drawings shall be prepared for each of the following branches of work.

(A) Architectural plans. Architectural drawings shall include the following:

(i) a map of the area within a two-mile radius of the facility site shall be provided and any hazardous and undesirable location noted in §133.162(a) of this title (relating to New Construction Requirements) shall be identified;

(ii) site plan showing all new topography, newly established levels and grades, existing structures on the site (if any), new buildings and structures, roadways, parking, walks, easement, overhead or underground utilities or service lines, and the extent of the areas to be landscaped. All structures which are to be removed under the construction contract and improvements shall be shown. A general description of the immediate area surrounding the site shall be provided;

(iii) plan of each floor and roof to include fire and smoke separation, means of egress, and identification of all spaces;

(iv) schedules of doors, windows, and finishes;

(v) elevations of each facade;

(vi) sections through building; and

(vii) scaled details as necessary.

(B) Fire safety plans. These drawings shall be provided for all newly constructed buildings, conversions of existing buildings for facilities, additions to existing licensed facilities, and remodeled portions of existing buildings containing licensed facilities. Fire safety plans shall be of a sufficiently large-scale to clearly illustrate the proposed design but not less than one-sixteenth inch equals one foot and shall include the following information:

(i) separate fire safety plans (preferably one floor plan per sheet) shall indicate location of fire protection rated walls and partitions, location and fire resistance rating of each fire damper, and the required means of egress (corridors, stairs, exits, exit passageways);

(I) when a new building is to contain a proposed facility, when an existing building is converted to a facility, or when an addition is made to an existing facility building, plans of each floor and roof shall be provided;

(II) when a portion of a building is remodeled or when a new service is added, only the plan of the floor where the remodeling will take place or new service will be introduced and the plan of the floor of discharge shall be provided;

(ii) designated smoke compartments with floor areas of each compartment, location and fire resistance rating (one or two hour) of each smoke partition, location, type and fire resistance rating of each smoke damper;

(iii) location of all required fire alarm devices, including all fire alarm control panels, manual pull stations, audible and visual fire alarm signaling devices, smoke detectors (ceiling and duct-mounted), fire alarm annunciators, fire alarm transmission devices, fire sprinkler flow switches and control valve supervisory switches on each of the floor plans; and

(iv) areas protected with fire sprinkler systems (pendant, sidewall or upright, normal or quick response, and temperature rating shall be indicated), stand pipe system risers and sizes with valves and inside and outside fire department connections, fire sprinkler risers and sizes, location and type of portable fire extinguishers.

(C) Equipment drawings. Equipment drawings shall include the following:

(i) all equipment necessary for the operation of the facility as planned. The design shall indicate provisions for the installation of large and special items of equipment and for service accessibility;

(ii) fixed equipment (equipment which is permanently affixed to the building or which must be permanently connected to a service distribution system designed and installed during construction for the specific use of the equipment). The term "fixed equipment" includes items such as laundry extractors, walk-in refrigerators, communication systems, and built-in casework (cabinets);

(iii) movable equipment (equipment not described in clause (ii) of this subparagraph as fixed). The term "moveable equipment" includes wheeled equipment, plug-in type monitoring equipment, and relocatable items; and

(iv) equipment which is not included in the construction contract but which requires mechanical or electrical service connections or construction modifications. The equipment described in this clause shall be identified on the drawings to ensure its coordination with the architectural, mechanical, and electrical phases of construction.

(D) Structural drawings. Structural drawings shall include:

(i) plans for foundations, floors, roofs, and all intermediate levels;

(ii) a complete design with sizes, sections, and the relative location of the various members;

(iii) a schedule of beams, girders, and columns;

(iv) dimensioned floor levels, column centers, and offsets;

(v) details of all special connections, assemblies, and expansion joints; and

(vi) special openings and pipe sleeves dimensioned or otherwise noted for easy reference.

(E) Mechanical drawings. Mechanical drawings shall include:

(i) complete ventilation systems (supply, return, exhaust), all fire and smoke partitions, locations of all dampers, registers, and grilles, air volume flow at each device, and identification of all spaces (e.g. corridor, patient room, operating room);

(ii) boilers, chillers, heating and cooling piping systems (steam piping, hot water, chilled water), and associated pumps;

(iii) cold and warm water supply systems, water heaters, storage tanks, circulating pumps, plumbing fixtures, emergency water storage tank(s) (if provided), and special piping systems such as for deionized water;

(iv) nonflammable medical gas piping (oxygen, compressed medical air, vacuum systems, nitrous oxide), emergency shutoff valves, pressure gages, alarm modules, gas outlets;

(v) drain piping systems (waste and soiled piping systems, laboratory drain systems, roof drain systems);

(vi) fire protection piping systems (sprinkler piping systems, fire standpipe systems, water or chemical extinguisher piping system for cooking equipment);

(vii) piping riser diagrams, equipment schedules, control diagrams or narrative description of controls, filters, and location of all duct-mounted smoke detectors; and

(viii) laboratory exhaust and safety cabinets.

(F) Electrical drawings. Electrical drawings shall include:

(i) electrical service entrance with service switches, service feeders to the public service feeders, and characteristics of the light and power current including transformers and their connections;

(ii) location of all normal electrical system and essential electrical system conduits, wiring, receptacles, light fixtures, switches and equipment which require permanent electrical connections, on plans of each building level:

(I) light fixtures marked distinctly to indicate connection to critical or life safety branch circuits or to normal lighting circuits; and

(II) outlets marked distinctly to indicate connection to critical, life safety or normal power circuits;

(iii) telephone and communication, fixed computers, terminals, connections, outlets, and equipment;

(iv) nurses calling system showing all stations, signals, and annunciators on the plans;

(v) in addition to electrical plans, single line diagrams prepared for:

(I) complete electrical system consisting of the normal electrical system and the essential electrical system including the on-site generator(s), transfer switch(es), emergency system (life safety branch and critical branch), equipment system, panels, subpanels, transformers, conduit, wire sizes, main switchboard, power panels, light panels, and equipment for additions to existing buildings, proposed new facilities, and remodeled portions of existing facilities. Feeder and conduit sizes shall be shown with schedule of feeder breakers or switches;

(II) complete nurses calling system with all stations, signals, annunciators, etc. with room number noted by each device and indicating the type of system (nurses regular calling system, nurses emergency calling system, or staff emergency assistance calling system);

(III) a single line diagram of the complete fire alarm system showing all control panels, signaling and detection devices and the room number where each device is located; and

(vi) schedules of all panels indicating connection to life safety branch, critical branch, equipment system or normal system, and connected load at each panel.

(3) Construction document changes. Any changes to the final construction documents which affect or change the function, design, or designated use of an area shall be submitted to the department for approval prior to authorization of the modifications.

(g) Special submittals.

(1) Self-certification.

(A) In an effort to shorten the plan review and approval process, the hospital owner/operator or representative may request approval of final construction documents under the self-certification review process.

(i) The owner/operator shall submit the items in subsection (b)(1)(A) - (D) of this section and a completed self-certification form, signed by the hospital owner/operator, architect of record, and engineer(s) of record attesting that the plans and specifications are based upon and comply with the requirements of this chapter.

(ii) By signing and submitting the self-certification form, the hospital owner/operator accepts the following conditions.

(I) The department retains the right to review the final construction documents, conduct inspections of the project, and withdraw its approval.

(II) The hospital owner/operator has a continuing obligation to make any changes the department requires to comply with the licensing rules whether or not physical plant construction or alterations have been completed.

(III) The hospital owner/operator is ultimately responsible for compliance with the Texas Hospital Licensing Law (Health and Safety Code, Chapter 241) and this chapter.

(B) The department will review the request for self-certification and notify the hospital owner/operator if the request is approved or denied. If denied, the department will review the final construction documents in the chronological order in which the documents were received. Construction may not begin until the final construction documents have been reviewed and approved.

(2) Fast-track project. At the discretion of the department, projects for new hospitals or major new additions may be allowed to submitted under the fast-track project in not more than three separate packages. A fast-track project shall be requested in writing on facility letterhead, signed by hospital administration, with a brief written description and narrative of the proposed project. Construction may not begin until the first package has been approved by the department.

(A) First package. The first package shall include:

(i) the items in subsection (b)(1)(A) - (C) of this section;

(ii) a map showing the location of the proposed facility site and adjacent surrounding area at least two miles in radius identifying any hazardous and undesirable location noted in §133.162(a) of this title;

(iii) preliminary architectural plans and a detailed building site plan showing all adjacent streets, site work, underslab mechanical, electrical, and plumbing work, and related specifications; and

(iv) foundation and structural plans.

(B) Second package. The second package shall include complete architectural plans and details with specifications and fire safety plans as described in subsection (f)(1) and (2)(A) - (D) of this section.

(C) Third package. The third package shall include complete mechanical, electrical, equipment and furnishings, and plumbing plans and specifications, as described in subsection (f)(1) and (2)(E) and (F) of this section. Package three may be submitted with the second package.

(3) Minor project. If a hospital owner/operator believes that a proposed project is a minor project as described in §133.161(a)(2)(C) of this title (relating to Requirements for Buildings in which Existing Licensed Hospitals are Located), the hospital owner/operator shall provide to the department a brief written description of the proposed project and floor plans of the areas of work.

(A) If it is determined that the proposed project is a minor project, the department will notify the hospital owner/operator of the approval, and state the number of inspections that will be required. A minimum of one inspection will be conducted.

(B) The department will notify the hospital owner/operator that a proposed project is not approved as a minor project if the project involves any of the following:

(i) remodeling or alterations which involve alterations to load bearing members or partitions;

(ii) a change in functional operation;

(iii) affects fire safety (e.g. modifications to the fire, smoke, and corridor walls);

(iv) adds beds or services for which the hospital is not currently licensed; and

(v) significantly changes the mechanical, electrical, plumbing, fire protection, or piped medical system.

(C) The hospital owner/operator shall submit final construction documents in accordance with subsection (f) of this section if the department determines the project is not a minor project.

(4) Fire sprinkler systems.

(A) When the sole purpose of a project is installation of a sprinkler system, whether a partial or complete system, the hospital owner/operator shall submit to the department for approval the items in subsection (b)(1)(A)-(C) of this section and sprinkler documents.

(B) Fire sprinkler systems shall comply with the requirements of National Fire Protection Association 13, Standard for the Installation of Sprinkler systems, 2002 edition (NFPA 13), and shall be designed or reviewed by an engineer who is registered by the Texas Board of Professional Engineers in fire protection specialty or is experienced in hydraulic design and fire sprinkler system installation. A short resume shall be submitted if registration is not in fire protection specialty.

(i) Fire sprinkler working plans, complete hydraulic calculations and water supply information shall be prepared in accordance with NFPA 13, §§14.1, 14.2 and 14.3, for new fire sprinkler systems, alterations of and additions to existing ones.

(ii) One set of fire sprinkler working plans, calculations and water supply information shall be forwarded to the department together with the professional engineer's (P.E. licensed in the state of Texas) certification letter stating that the sprinkler system design complies with the requirements of NFPA 13. Certification of the fire sprinkler system shall be submitted prior to system installation.

(iii) Upon completion of the fire sprinkler system installation and any required corrections, written certification by the engineer, stating that the fire sprinkler system is installed in accordance with NFPA 13 requirements, shall be submitted prior to or with the written request for the final construction inspection of the project.

(h) Retention of drawings, manuals and design data.

(1) As built drawings. Upon occupancy of the building or portion thereof, the owner shall retain as part of the hospital's permanent records, a complete set of legible architectural plans of each building level, fire safety plans as described in subsection (f)(2)(B) of this section for each floor reflecting fire safety requirements, and all single line diagrams described in subsection (f)(2)(F)(v) of this section, drawings for fixed equipment, and mechanical and electrical systems, as installed or built.

(2) Manuals. Upon completion of the contract, the owner shall retain as part of the hospital's permanent records a complete set of manufacturers' operating, maintenance, and preventive maintenance instructions; parts lists; and procurement information with numbers and a description for each piece of equipment. Facility staff shall also be provided with instructions on how to properly operate systems and equipment. Required information shall include energy ratings as needed for future conservation calculations.

(3) Design data. The owner shall retain in the hospital's permanent records complete design data for the facility. This shall include structural design loadings; summary of heat loss assumption and calculations; estimated water consumption; medical gas outlet listing; list of applicable codes; and electric power requirements of installed equipment. All such data shall be supplied to facilitate future alterations, additions, and changes, including, but not limited to, energy audits and retrofit for energy conservation.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on June 1, 2007.

TRD-200702151
Lisa Hernandez
Deputy General Counsel
Department of State Health Services
Effective date: June 21, 2007
Proposal publication date: December 15, 2006
For further information, please call: (512) 458-7111 x6972

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TITLE 37. PUBLIC SAFETY AND CORRECTIONS

PART 6. TEXAS DEPARTMENT OF CRIMINAL JUSTICE

CHAPTER 159. SPECIAL PROGRAMS

37 TAC §159.17

The Texas Board of Criminal Justice (TBCJ) adopts new rule, Title 37, Part 6, Chapter 159, Special Programs, §159.17, Employment Referral Services for Offenders, which authorizes the Agency to adopt a memorandum of understanding (MOU) between the Texas Department of Criminal Justice (TDCJ), the Texas Workforce Commission (TWC), the Texas Youth Commission (TYC) and the Windham School District (WSD), without changes as proposed in the April 13, 2007, issue of the *Texas Register* (32 TexReg 2130).

The purpose of the rule is to establish the responsibilities of each agency in the administration of the Project for Reintegration of Offenders (Project RIO).

No comments were received.

The new rule is adopted under Texas Government Code, §501.095 and Texas Labor Code, §306.004 and §306.005.

Cross Reference to Statutes: Texas Education Code, §19.011 and Texas Government Code §771.001, et seq.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on May 25, 2007.

TRD-200702095
Melinda Hoyle Bozarth
General Counsel
Texas Department of Criminal Justice
Effective date: June 14, 2007
Proposal publication date: April 13, 2007
For further information, please call: (512) 463-0422

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TITLE 40. SOCIAL SERVICES AND ASSISTANCE

PART 1. DEPARTMENT OF AGING AND DISABILITY SERVICES

CHAPTER 79. LEGAL SERVICES

The Health and Human Services Commission (HHSC), on behalf of the Department of Aging and Disability Services (DADS), adopts the repeal of §§79.101 - 79.105, 79.201 - 79.210, and 79.301 - 79.305, in Chapter 79, Legal Services, without changes to the proposal as published in the March 30, 2007, issue of the *Texas Register* (32 TexReg 1896).

The repeal is adopted to comply with Acts 2003, 78th Legislature, Regular Session, Chapter 198 (House Bill 2292), §1.18 and §1.26, which abolished the Texas Department of Human Services and the Board of Human Services, effective September 1, 2004; and with Texas Government Code, §531.0055, which vests rulemaking authority for all health and human services agencies, including DADS, with the HHSC executive commissioner. The repeal of §§79.101 - 79.105 eliminates obsolete rules governing the rules of practice before the Board of Human Services, because that board no longer exists. The repeal of §§79.201 - 79.210 and §§79.301 - 79.305 eliminates obsolete rules governing rulemaking procedures, because rulemaking authority has been transferred to the HHSC executive commissioner.

DADS received no comments regarding adoption of the repeal.

SUBCHAPTER B. RULES OF PRACTICE BEFORE THE STATE BOARD OF HUMAN SERVICES

40 TAC §§79.101 - 79.105

The repeal is adopted under Texas Government Code, §531.0055, which provides that the HHSC executive commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including DADS; and Texas Human Resources Code, §161.021, which provides that the Aging and Disability Services Council shall study and make recommendations to the HHSC executive commissioner and the DADS commissioner regarding rules governing the delivery of services to persons who are served or regulated by DADS.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on May 31, 2007.

TRD-200702123
Kenneth L. Owens
General Counsel
Department of Aging and Disability Services
Effective date: June 20, 2007
Proposal publication date: March 30, 2007
For further information, please call: (512) 438-3734

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SUBCHAPTER C. PROCEDURE FOR PUBLIC HEARINGS ON PROPOSED SUBSTANTIVE RULES

40 TAC §§79.201 - 79.210

The repeal is adopted under Texas Government Code, §531.0055, which provides that the HHSC executive commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including DADS; and Texas Human Resources Code, §161.021, which provides that the Aging and Disability Services Council shall study and make recommendations to the HHSC executive commissioner and the DADS commissioner regarding rules governing the delivery of services to persons who are served or regulated by DADS.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on May 31, 2007.

TRD-200702124
Kenneth L. Owens
General Counsel
Department of Aging and Disability Services
Effective date: June 20, 2007
Proposal publication date: March 30, 2007
For further information, please call: (512) 438-3734

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SUBCHAPTER D. RULEMAKING PROCEDURES

40 TAC §§79.301 - 79.305

The repeal is adopted under Texas Government Code, §531.0055, which provides that the HHSC executive commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including DADS; and Texas Human Resources Code, §161.021, which provides that the Aging and Disability Services Council shall study and make recommendations to the HHSC executive commissioner and the DADS commissioner regarding rules governing the delivery of services to persons who are served or regulated by DADS.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

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TRD-200702125
Kenneth L. Owens
General Counsel
Department of Aging and Disability Services
Effective date: June 20, 2007
Proposal publication date: March 30, 2007
For further information, please call: (512) 438-3734

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CHAPTER 100. MISCELLANEOUS

The Health and Human Services Commission (HHSC), on behalf of the Department of Aging and Disability Services (DADS), adopts the repeal of §§100.5, 100.7, 100.24, 100.35, and 100.301 - 100.308, in Chapter 100, Miscellaneous, without changes to the proposal as published in the March 30, 2007, issue of the *Texas Register* (32 TexReg 1898).

The repeal is adopted to comply with Acts 2003, 78th Legislature, Regular Session, Chapter 198 (House Bill 2292), §1.18 and §1.26, which abolished the Texas Department of Mental Health and Mental Retardation (TDMHMR), the Texas Department on Aging, the TDMHMR Board, and the Texas Board on Aging. Rules governing the former agencies' activities were transferred to DADS on September 1, 2004.

The repeal of §100.5 and §100.7 is adopted to delete obsolete rules from DADS' rule base, because the Texas Board on Aging and its advisory councils no longer exist.

The repeal of §100.24 and §100.35 is adopted to delete duplicative rules governing employee training and historically underutilized businesses. The remaining sections governing employee training, which are required by Texas Government Code, §656.048, are found in 40 TAC Chapter 77. The remaining section governing historically underutilized businesses is found at 40 TAC §69.15.

The repeal of §§100.301 - 100.308 is adopted to eliminate obsolete rules governing TDMHMR rulemaking procedures, because the HHSC executive commissioner has sole rulemaking authority for DADS.

DADS received no comments regarding adoption of the repeal.

SUBCHAPTER A. OPERATION OF THE TEXAS DEPARTMENT ON AGING

40 TAC §§100.5, 100.7, 100.24, 100.35

The repeal is adopted under Texas Government Code, §531.0055, which provides that the HHSC executive commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including DADS; and Texas Human Resources Code, §161.021, which provides that the Aging and Disability Services Council shall study and make recommendations to the HHSC executive commissioner and the DADS commissioner regarding rules governing the delivery of services to persons who are served or regulated by DADS.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

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Kenneth L. Owens
General Counsel
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Effective date: June 20, 2007
Proposal publication date: March 30, 2007
For further information, please call: (512) 438-3734

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SUBCHAPTER G. TDMHMR RULEMAKING

40 TAC §§100.301 - 100.308

The repeal is adopted under Texas Government Code, §531.0055, which provides that the HHSC executive commissioner shall adopt rules for the operation and provision of services by the health and human services agencies, including DADS; and Texas Human Resources Code, §161.021, which provides that the Aging and Disability Services Council shall study and make recommendations to the HHSC executive commissioner and the DADS commissioner regarding rules governing the delivery of services to persons who are served or regulated by DADS.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

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Kenneth L. Owens
General Counsel
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For further information, please call: (512) 438-3734

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PART 20. TEXAS WORKFORCE COMMISSION

CHAPTER 809. CHILD CARE SERVICES

SUBCHAPTER E. REQUIREMENTS TO PROVIDE CHILD CARE

40 TAC §809.91

The Texas Workforce Commission (Commission) adopts amendments, with changes, to the following section of Chapter 809 relating to Child Care Services, as published in the February 16, 2007, issue of the *Texas Register* (32 TexReg 608):

PART I. PURPOSE, BACKGROUND, AND AUTHORITY

The Commission is entrusted by the citizens of the state of Texas to be a responsible steward of public funds. The Commission takes this responsibility seriously, particularly concerning the health and safety of children. The receipt of public child care funds includes the responsibility to ensure that child care is provided in a safe environment. With the exception of the requirements specifically applicable to relative child care providers, Commission rules ensure that the health and safety of children receiving Commission-funded child care services are protected by requiring that child care providers that care for children in Commission-funded child care--i.e., licensed child care centers, licensed child care homes, and registered child care homes--be subject to state-mandated and federally required health and safety standards under the supervision of the Texas Department of Family and Protective Services (DFPS). These standards include requiring immunizations for children, conducting periodic health and safety inspections, as well as conducting background checks for criminal history, and checking the Child Protective Services' (CPS) child abuse registry (Texas Human Resources Code, Chapter 42).

Child Care and Development Fund (CCDF) regulations, however, allow states to exempt children who are cared for by relatives from federally mandated minimum health and safety standards (45 C.F.R. §98.41(e)). In the preamble to the CCDF regulations, the Administration for Children and Families (ACF) expressly states that the "intent of the statute was to give grantees (states) the option to exempt certain relatives from the health and safety requirements that all other CCDF child care providers must meet" (*Federal Register*, Vol. 63, No. 142, July 24, 1998, at 39957, or CCDF preamble). The Commission is firmly committed to the principle of parent choice and believes that parents have the right to choose the type of child care provider that best meets their needs, including relative providers. However, the principle of parent choice does not override the principle of ensuring the health and safety of children receiving publicly funded child care services.

Federal regulations also allow states to impose more stringent requirements on child care service providers that receive assistance under CCDF than those requirements imposed on other child care providers, as long as those additional requirements are consistent with the safeguards for parental choice (45 C.F.R. §98.40). Other than prohibiting an individual who appears on the Texas Department of Public Safety's (DPS) Sex Offender Registry from being an eligible relative child care provider, the Commission has not established more stringent requirements for relative child care providers, and as such, these providers are not subject to criminal background checks or child abuse registry checks, as other regulated and listed providers are. Further, the CCDF preamble provides that "with respect to criminal background checks . . . (ACF agrees) that it is appropriate to encourage States to adopt criminal background checks as part of their effort to meet CCDF health and safety standards" (CCDF preamble at 39956). In light of the flexibility afforded states under the CCDF regulations, the Commission has determined that additional requirements for unregulated relative child care providers can be incorporated into existing rules to the extent allowed under state law.

In Texas, family homes listed with DFPS are subject to background checks. A family home is defined in §42.002(9) of the Texas Human Resources Code as:

"a home that provides regular care in the *caretaker's own residence* for not more than six children under 14 years of age, excluding children who are related to the caretaker, and that provides care after school hours for not more than six additional elementary school children, but the total number of children, including children who are related to the caretaker, does not exceed 12 at any given time. *The term does not include a home that provides care exclusively for any number of children who are related to the caretaker.*" (emphasis added)

While §42.002(9) of the Texas Human Resources Code appears to exempt providers that care exclusively for children who are related to the provider from the definition of "family home," and Texas Human Resources Code §42.052(d) states that a family home that provides care exclusively for any number of children related to the caretaker is not required to be listed or registered with DFPS, neither provision prohibits a relative care provider from being listed with DFPS.

Furthermore, DFPS rule at 40 TAC §745.141 states that a child care operation that is considered exempt from DFPS regulations may still apply for a permit from DFPS if the operator is required to have a permit to receive public funding. Therefore, if the Commission requires relative child care providers to list with DFPS as a prerequisite to receiving Commission funds, relative child care providers--based on DFPS rules--will be required to have a criminal background check conducted by DFPS. DFPS agreed that, under the DFPS rule mentioned above, relatives providing Commission-funded child care services may apply for a permit to be a listed family home in order to receive the public funds. However, DFPS clarified that the relative applying for a listed family home permit still must meet the requirement in the definition of a family home that the listed home be *the caretaker's own residence*.

Thus, if the relative child care provider is providing care exclusively in the child's own home (in-home care) and *not* in the relative's own home, then the relative provider does not meet the definition of a family home (i.e., the care is not in the caretaker's own residence) and cannot apply for a permit to be a listed family home. Therefore, the Commission cannot require a relative be listed with DFPS if the relative is providing care outside his or her home.

Based on this information, the Commission has modified the rule language to specify that relatives caring for children in the relative's residence must be listed with DFPS. The rule language also states that if the care is not in the relative's residence, but in the child's own home, then the relative will not be required to list with DFPS. However, the Commission retains the provision in the current rule stating that the relative caring for a child in the child's residence (but not in the relative's residence) must not appear on the DPS Sex Offender Registry.

Because CCDF regulations at 45 C.F.R. §98.30(e) require states to allow in-home care, the Commission, at this time, does not require all relative care to take place in the relative's residence and be listed with DFPS. However, CCDF regulations do allow states to place limitations on in-home care. The Commission will monitor the use of care provided in the child's residence. Based on that information, future rule amendments may be considered, consistent with state and federal regulations.

The Commission has fully examined both state and federal regulations regarding criminal and child abuse background checks and analyzed the feasibility of requiring background checks of relative providers before authorizing Commission-funded child care. Commission rules allow parents the right to choose a relative provider (eligible under 45 C.F.R. §98.2 and §809.91 of this chapter), but the Commission has concluded that a parent's right to choose a relative provider cannot come at the expense of placing that child in a home with someone whose criminal history or appearance in the CPS central registry of child abuse and neglect may indicate the individual could potentially endanger the child, particularly when this placement is government funded.

Therefore, the Commission adopts rules to require that relative child care providers caring for a child in the relative's residence be listed with DFPS, and in doing so, to make these relative providers subject to criminal background checks, CPS central registry searches, and facility inspection in the event of a complaint of suspected child abuse or neglect.

Approximately 10,000 relative providers care for children receiving Commission-funded child care services during any given month, not accounting for the location of the care. Furthermore, approximately 1,250 such relative providers come into the subsidized child care system each month. By contrast, DFPS reports that there are approximately 3,895 listed family homes (DFPS *2006 Data Book*) and 118 requests per month to be a listed family home. The Commission recognizes that the adopted rules will lead to a substantial increase in the DFPS workload in order to conduct the background checks for relative child care providers. The Commission also recognizes that DFPS will need increased resources to assist in the implementation of the new rules and the Commission is committed to working with DFPS to help that agency meet its resource needs.

PART II. EXPLANATION OF INDIVIDUAL PROVISIONS

The Commission adopts the following amendments:

Section 809.91(b) provides the requirements for child care providers listed with DFPS. Section 809.91(b)(1) states that Local Workforce Development Boards (Boards) shall not prohibit a relative child care provider who is listed with DFPS and meets the eligibility requirements of §809.91 from being an eligible relative child care provider. The Commission includes this statement to clarify that although §809.91(b)(2) allows Boards the option to include listed family homes as eligible child care providers if the Boards ensure that there are local requirements designed to protect the health and safety of children, Boards do not have the option to exclude relative providers listed with DFPS as eligible relative child care providers.

Section 809.91(b)(2) gives Boards the option to include listed family homes as eligible providers, as long as the Boards ensure that there are local laws in effect that protect the health and safety of children. The Commission adds language to clarify that this option applies only to listed family homes, as defined in §809.2(12) of this chapter, that provide care for children unrelated to the provider. This provision is consistent with 45 C.F.R. §98.41(e), which does not allow states to exempt non-relative child care providers from health and safety standards.

Section 809.91(f), which prohibits an individual who appears on the DPS Sex Offender Registry from being an eligible relative child care provider, is removed. This provision is removed because for relative providers who are listed with DFPS this function effectively will be implemented through the criminal background check conducted by DFPS. However, due to the clarification received from DFPS regarding its regulatory authority for listed family homes, the requirement prohibiting an individual ap-

pearing on the DPS Sex Offender Registry from being an eligible relative provider is retained in new §809.91(f)(2) for relative care provided in the child's own home.

New §809.91(f)(1) is a broader provision designed to ensure that prior to authorizing care with the relative provider who will be caring for a child in the relative's own residence, a more comprehensive background check on a relative child care provider is conducted by DFPS using DFPS criteria for listed family homes. The new subsection requires that relative child care providers caring for a child in the relative's own residence shall list with DFPS to ensure that a criminal background check and a check of the CPS central registry is conducted prior to authorizing care with that relative. Furthermore, the requirements for a listed family home include a criminal history and background check for each person 14 years of age or older who will regularly or frequently be staying or working at the home while children are being provided care. Therefore, Commission rules requiring relative providers who are caring for a child in the relative's residence to be listed with DFPS require that all adults residing in or regularly staying or working at the home will be subject to a criminal history and background check.

The Commission emphasizes that the criminal background check and the check of individuals on the CPS central registry of child abuse and neglect will be conducted by DFPS using its current application and background check procedures for listed family homes. The Commission does not intend for a Board or a Board's child care contractor to conduct any of the functions associated with the listing process.

Prior to authorizing child care, the child care contractor must inform the parent that a prospective relative caring for a child in the relative's home must be listed with DFPS and provide the application-or notify the relative how to access the application-for listing with DFPS. The relative must submit the application along with the $20 annual fee to DFPS and DFPS will conduct the necessary background checks. If there is no criminal history match or match on the CPS central registry of child abuse and neglect, DFPS will inform the relative that no matches occurred and will issue a listing to the relative. Once the listing is issued, the relative will be eligible to provide Commission-funded child care services for the eligible child. DFPS has informed the Commission that background checks usually are completed within 48 hours and the listing issued to the relative within one week of receiving the application. The Board's sole responsibility is to ensure that the child care contractor verifies that the relative is listed with DFPS, which can be authenticated by viewing the listing permit that DFPS provides to the relative. DFPS also has informed the Commission that once the listing is issued, the DFPS Web site is updated the next day, and the child care contractor can verify the listing through the Web site.

The Commission emphasizes that the child care contractor cannot authorize the relative to receive Commission child care funds until DFPS issues the listing to the relative. Additionally, the Commission does not intend that relative child care providers be reimbursed retroactively for child care provided to the eligible child by the relative pending the results of the DFPS background checks.

In addition, new §809.91(f)(1) states that in all other respects, relatives listed with DFPS are exempt from the CCDF health and safety requirements at 45 C.F.R. §98.41(a). This provision is consistent with 45 C.F.R. §98.41(e), which allows states to exempt relative child care providers from health and safety standards. Specifically, other than the background checks required of child care providers listing with DFPS, relative providers who care for children receiving Commission-funded child care services are exempt from standards related to the prevention and control of infectious disease; building and physical premises safety; and minimum health and safety training.

New §809.91(f)(2) retains the provision that Boards must ensure that an individual appearing on the DPS Sex Offender Registry is not an eligible relative child care provider. However, pursuant to comments received from DFPS, new §809.91(f)(2) clarifies that this provision applies only to relatives providing care in the child's own residence. Again, the Commission emphasizes that for relatives providing care in the relative's residence, a broader criminal history and background check, which includes a sex offender check, is performed by DFPS as part of the listing process required by §809.91(f)(1).

Comment: Five commenters supported the rule change. Two of the commenters stated that the rule would reduce the risk of abuse and neglect for children served through their subsidized child care programs. Another commenter stated that this rule change is a significant step toward protecting the health and safety of children receiving care through the child care subsidy program.

Response: The Commission appreciates the support of the rules.

Comment: One commenter stated that the rule language will require a background check only on the relative provider and requested that the Commission expand this to include all adults residing in the home.

Response: The Commission appreciates the comment and clarifies that §42.056 of the Texas Human Resources Code, and related DFPS regulations, require that the background check for providers listing with DFPS must include "each person 14 years of age or older who will regularly or frequently be staying or working at the facility or home while children are being provided care." Therefore, Commission rules requiring relative providers to be listed with DFPS require that all adults residing in or regularly staying or working at the home will be subject to a background check.

Comment: One commenter noted that the preamble stated that the relative provider will pay DFPS an annual $20 fee but it was unclear whether a background check will be performed each year or only initially.

Response: The Commission appreciates the comment and clarifies that §42.056 of the Texas Human Resources Code, and related DFPS regulations, require that the background check for providers listing with DFPS be conducted at least once every two years.

Comment: One commenter expressed concern about the costs to the relative provider associated with being listed with DFPS. The commenter stated that while the $20 yearly fee and the cost of carbon monoxide detectors may seem minimal to some, many low-income relative providers may not be able to absorb such costs and thus will reject a job opportunity.

Response: While the Commission recognizes the concerns, the Commission strongly believes in protecting the health and safety of children cared for with public funds. Further, Texas Human Resources Code §42.060, and related DFPS regulations, require the use of carbon monoxide detectors in certain child care settings. The Commission points out that reliable carbon monoxide detectors can be purchased for $25 and believes that the

long-term safety benefits of a carbon monoxide detector in the home far outweigh the $25 onetime cost. Additionally, the Commission believes that the $20 annual fee required by DFPS is a reasonable cost and that the costs associated with listing with DFPS can be absorbed by the relative through the child care subsidy paid to the relative by the Commission.

Comment: One commenter stated that as long as federal regulations permit relative care (as provided in 45 C.F.R. §98.41), neither the Boards nor their child care contractors have any control over which relatives may visit or live in a home (without registering with DPS) while children are under the supervision of the *one* relative that was predetermined eligible by DFPS.

Response: The Commission appreciates the comment and is aware of the reality of certain family situations. The Commission acknowledges that children may regularly come into contact or even reside with relatives who have a criminal background, including relatives registered with DPS as sex offenders. However, as stated in the preamble, the Commission is entrusted by the citizens of the state of Texas to be a responsible steward of public funds. This is particularly important in the provision of publicly funded child care services, which involve the health and safety of children. The receipt of public child care funds includes the responsibility to ensure that child care is provided in a safe environment. As mentioned previously, DFPS rules regarding listed family homes reflect state law requiring a background check for each person 14 years of age or older who will regularly or frequently be staying or working at the home while children are being provided care. Although the adopted rules will not completely prevent children from coming into contact with relatives with a criminal background, by requiring a background check for anyone who regularly frequents the home, the rules are designed to minimize the risk of children who receive publicly funded child care services being placed in potentially unsafe environments.

Comment: One commenter requested clarification regarding allegations of abuse and neglect. The commenter stated that local licensing staff indicated that they do not typically make visits of this type when relative care is involved. The commenter asked if this type of situation will then be turned over to CPS for investigation.

Response: The Commission has consulted with DFPS on this matter and DFPS has indicated that any reported allegation of abuse and neglect at a relative child care provider site listed with DFPS will be investigated by both Child Care Licensing and CPS. Child Care Licensing will investigate the report for possible abuse and neglect violations based on licensing standards, while CPS will investigate the report based on child protective standards.

Comment: One commenter expressed concerns with the safety, feasibility, and practicality if the child care contractor were required to monitor relative care providers in their homes. The commenter believed that such a task would require additional labor costs because there would need to be at least two child care contractor representatives to enter a private residence. The commenter further stated that there is still a potential danger when two or more child care representatives enter the residence to monitor the relative child care provider.

Response: The Commission emphasizes that the adopted rules do not require child care contractors to monitor the care provided in a relative's home for compliance with DFPS regulations. As stated previously, the criminal background check and the check of individuals on the CPS central registry of child abuse and neglect will be conducted by DFPS using its current application and background check procedures for listed family homes. Additionally, any investigation of reported abuse or neglect will be conducted by DFPS. The Commission does not intend for a Board or a Board's child care contractor to conduct any of the functions associated with the listing process or with monitoring for compliance with DFPS rules or regulations.

Although these rules do not place requirements on Boards for monitoring compliance with DFPS rules or regulations, the Commission expects Boards to continue to implement their policies and procedures for researching and fact-finding for possible improper payments or suspected fraud as required by subchapter F of this chapter.

Comment: Three commenters supported the rules yet expressed concerns that the rules will have an adverse impact on the availability of subsidized child care, especially in rural areas. One of the commenters had discussions with another state that adopted a similar policy and was informed that there was a decrease in relative care-either relatives did not want to consent to a background check or they were not authorized because of their previous criminal or CPS history. Another commenter stated that many families with relative providers may cease to participate in the subsidy program-not as a result of the criminal background check, but because they feel it may not be cost effective, given lower reimbursement rates and costs to become a listed provider. If no viable child care is available, particularly in rural areas where there is a shortage of day care facilities, the impact on the labor force, the economy, and public assistance could become evident.

Two of the commenters were concerned that this impact on the availability of child care will affect the Board's ability to meet the performance measure for the number of children served. One of the commenters stated that the rule would increase a Board's average rate per child if eligible children are transferred to a more expensive licensed facility or registered home. One commenter stated that due to the lack of regulated child care facilities in the local workforce development area, the Board has no choice but to rely heavily upon relative care providers as a means to get individuals back to work and on track to self-sufficiency. A decrease in the number of relative care providers could impede the Board's ability to spend its child care dollars if such mandates are placed on relative care providers. The rules could adversely affect the Board's ability to meet its performance measure.

Response: The Commission appreciates the comments and understands the concerns. The Commission recognizes that the adopted rule may lead some current relative child care providers to discontinue the provision of Commission-funded child care services. The Commission also recognizes that the adopted rules may prevent some relatives who are currently providing Commission-funded child care services from being eligible providers because of the required background check. In these cases, some parents eligible for Commission-funded child care may choose to enroll their children in a regulated child care facility while others may choose to have their children remain with the relative, but not receive Commission funds. The Commission emphasizes that these child care choices remain solely with the parent.

The Commission is aware that there may be potential impact on Board performance as a result of relative providers deciding not to list with DFPS or relative providers who may not be eligible because of the results of the background check. However, the Commission maintains that it is not possible at this time to quan-

tify any anticipated impact on the cost of care or Board performance resulting from this rule. The Commission will work with the Boards to monitor and analyze any increased costs or adverse effects on Board performance. Furthermore, the Commission will monitor very closely any adverse impact the rule may have on the ability of parents in rural areas to secure adequate child care.

Comment: DFPS supported the intent of the rules to protect children through background checks of child care providers. However, DFPS stated that the listed family home category is designed for non-relative caregivers. The rules would result in DFPS regulating a category of caregivers otherwise outside of its regulatory language. DFPS expressed concern about the impact of a significant and unexpected workload. The estimated number of new providers requesting to become listed family homes per month is a substantial increase over the average number of requests to become a listed family home in Fiscal Year 2005. DFPS will not be able to support this influx of listed family home applicants without additional resources. DFPS stated that the new rules would require two background check workers and four background check technicians to process the listed family home applications and conduct the background checks. However, DFPS stated that the agency can absorb any additional abuse and neglect investigations with existing resources.

DFPS stated that even though the state would see a revenue increase in collected fees from the providers, it is important to note that §42.0521 of the Texas Human Resources Code requires that all fees collected by Child Care Licensing be deposited into the General Revenue fund. In order for the fee revenue to offset the costs of listing these relative care providers, the Legislature would need to appropriate these funds to DFPS.

Response: The Commission appreciates the comment and the support and input DFPS staff provided to the Commission in the development of these rules. The Commission believes that both agencies shared the same goal during this process-to protect the safety of children receiving publicly funded child care services. The Commission recognizes that the listed family home category is not designed for relative caregivers and that DFPS will need increased resources to assist the Commission in the implementation of the adopted rules.

The Commission is committed to working with DFPS to help it meet its resource needs. As the Commission discussed with DFPS during the development of these rules, the Commission intends to provide CCDF funds appropriated to the Commission to enable DFPS to conduct the background checks. The Commission does not anticipate that additional state resources will be needed. Again, the Commission appreciates the efforts of DFPS staff in working with the Commission to ensure that the integrity of public child care funds is maintained.

Comment: DFPS also submitted a verbal comment to explain that, pursuant to state law, the listed family home definition requires the care to be provided in the caretaker's own residence. DFPS stated that it does not list or otherwise regulate care provided outside the caretaker's own home. Thus, unless the care is provided in the relative's home, DFPS will not list the relative as a family home provider.

Response: The Commission appreciates the clarification and modifies the rule language in §809.91(f) to specify that relatives caring for a child in the relative's residence must list with DFPS, while relatives caring for a child in the child's residence, but outside of the relative's residence, must be subject to a check against the DPS Sex Offender Registry.

Comment: Two commenters expressed concerns related to the workload the adopted rules would have on DFPS. The commenters were concerned that DFPS will not be able to absorb the increased workload and as a result will take longer than one week. Delays from DFPS with these background checks will ultimately delay the Board's child care and workforce contractors from performing their services as efficiently as possible.

One commenter recommended that the rules be implemented immediately for new relative providers. For cases currently authorized with a relative provider, the commenter recommended that implementation be applied at the next recertification. If all current relative providers are given the same date to be listed, the commenter questioned whether DFPS will be able to maintain the current one-week time frame for processing listing applications and child care could be adversely affected by processing delays.

Response: The Commission appreciates the comments and recognizes that DFPS will require additional resources to assist in the implementation of the new rules. As mentioned previously, the Commission will continue to work with DFPS to help that agency meet its resource needs in order for it to conduct the background checks in a timely manner. The Commission will provide guidance to the Boards regarding the implementation timeline for these rules. The implementation of the rules will be based on ensuring that DFPS has acquired the necessary resources to conduct the required background checks.

Comment: One commenter requested that the Commission and DFPS develop a way to report to the Boards when relative providers have lost their listed status. Another commenter requested that the Commission modify the existing child care automated systems to include the date the relative provider was listed with DFPS and the date the listing expired. The commenter requested that the automated system include a report that will enable the Board to see when the listing is scheduled to expire.

Response: The Commission agrees with the comment. The Commission will work closely with DFPS to ensure that up-to-date information related to relative providers' listing status is provided to the Boards and the Boards' child care contractors on a regular basis. Additionally, the Commission will modify its child care automated systems to include the requested information and report.

Comment: Two commenters suggested that the Commission revise the definition of a relative in order to allow for relative providers in blended families, where two or more children have different noncustodial parents. Although not specifically mentioned in the rules, the definition of a relative provider in §809.2(18) defines a relative provider as an individual who is related to the child by marriage, blood relationship, or court decree. The commenters pointed out that many custodial parents frequently have children by more than one noncustodial parent. An example is if an unmarried mother has two children by different fathers, the rules would not allow the mother to place both children with one of the children's grandmothers. In this instance, if the mother chose relative care, she would have to select two relative providers.

The commenters requested that the Commission revise the definition of a relative so that an eligible relative provider must meet the criteria for at least one child. If a provider is an eligible relative

for one child in the family, through blood relationship with his or her noncustodial parent, the commenters recommended that the relative be able to provide care for that child's sibling too, even if not technically an eligible relative to the sibling. One of the commenters requested that the Commission add "in loco parentis" to the definition of relative provider. The commenters stated that this would greatly simplify the child care process for the single parent, if all children can be taken to the same provider, instead of possibly a different provider for each child.

Response: The Commission appreciates the comment and the desire to simplify the child care process as well as to keep half-siblings together in one care setting. However, as indicated in the comment, §809.2(18)-the definition of a relative child care provider-is not part of the rule amendments issued for public comment. Therefore, the Commission cannot address changes to that section. The Commission will research the applicable CCDF regulations and state law governing caregivers who are not related to the child by blood, marriage, or court order. The Commission will report the findings and provide guidance to the Boards on this issue.

COMMENTS WERE RECEIVED FROM:

Diana Spiser, Assistant Commissioner for Child Care Licensing, DFPS

Susan Ashmore, Director of Child Care Services, Alamo Workforce Development Board

Lizzy Bosell, Permian Basin Workforce Development Board

Joyce Sneed, Child Care Services Contractor Manager, Concho Valley Workforce Development Board

Susan Thomas, Rural Child Care Coordinator, Alamo Area Council of Governments

Susan Hoff, President, Child Care Group

The Agency hereby certifies that the adoption has been reviewed by legal counsel and found to be within the Agency's legal authority to adopt.

The rules are adopted under Texas Labor Code §301.0015 and §302.002(d), which provide the Commission the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of Agency services and activities, and the Texas Human Resources Code §44.002, regarding Administrative Rules.

The adopted rules will affect Texas Labor Code, Title 4, particularly Chapters 301 and 302, as well as Texas Government Code, Chapter 2308.

§809.91. Minimum Requirements for Providers.

(a) A Board shall ensure that child care subsidies are paid only to:

(1) regulated child care providers as described in §809.2(17);

(2) relative child care providers as described in §809.2(18), subject to the requirements in subsections (e) and (f) of this section; or

(3) at the Board option, listed family homes as defined in §809.2(12), subject to the requirements in paragraph (b)(2) of this section.

(b) For providers listed with DFPS, the following applies:

(1) A Board shall not prohibit a relative child care provider who is listed with DFPS and who meets the minimum requirements of this section from being an eligible relative child care provider.

(2) If a Board chooses to include listed family homes, as defined in §809.2(12), that provide care for children unrelated to the provider, a Board shall ensure that there are in effect, under local law, requirements applicable to the listed family homes designated to protect the health and safety of children. Pursuant to 45 C.F.R. §98.41, the requirements shall include:

(A) the prevention and control of infectious diseases (including immunizations);

(B) building and physical premises safety; and

(C) minimum health and safety training appropriate to the child care setting.

(c) Except as provided by the criteria for Texas Rising Star Provider Certification, a Board or the Board's child care contractor shall not place requirements on regulated providers that:

(1) exceed the state licensing requirements stipulated in Texas Human Resources Code, Chapter 42; or

(2) have the effect of monitoring the provider for compliance with state licensing requirements stipulated in Texas Human Resources Code, Chapter 42.

(d) When a Board or the Board's child care contractor, in the course of fulfilling its responsibilities, gains knowledge of any possible violation regarding regulatory standards, the Board or its child care contractor shall report the information to the appropriate regulatory agency.

(e) Relative child care providers shall not reside in the same household as the eligible child unless:

(1) the eligible child is a child of a teen parent; or

(2) the Board's child care contractor determines and documents that other child care provider arrangements are not reasonably available. Factors used to determine the reasonable availability of child care may include, but are not limited to:

(A) the parent's work schedule;

(B) the availability of adequate transportation; or

(C) the age of the child.

(f) For relative child care providers to be eligible for reimbursement for Commission-funded child care services, the following applies:

(1) Relative child care providers caring for a child in the relative's own residence shall list with DFPS; however, pursuant to 45 C.F.R. §98.41(e), relative child care providers listed with DFPS shall be exempt from the health and safety requirements of 45 C.F.R. §98.41(a);

(2) For relative child care providers caring for a child in the child's own residence, Boards shall ensure that the relative child care provider does not appear on the Texas Department of Public Safety's Sex Offender Registry, pursuant to Chapter 62 of the Texas Code of Criminal Procedure.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on June 4, 2007.

TRD-200702210

Reagan Miller

Deputy Division Director for Workforce Policy and Service Delivery Branch

Texas Workforce Commission

Effective date: June 24, 2007

Proposal publication date: February 16, 2007

For further information, please call: (512) 475-0829

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REVIEW OF AGENCY RULES

This section contains notices of state agency rules review as directed by the Texas Government Code, §2001.039. Included here are (1) notices of *plan to review;* (2) notices of *intention to review,* which invite public comment to specified rules; and (3) notices of *readoption,* which summarize public comment to specified rules. The complete text of an agency's *plan to review* is available after it is filed with the Secretary of State on the Secretary of State's web site (http://www.sos.state.tx.us/texreg). The complete text of an agency's rule being reviewed and considered for *readoption* is available in the *Texas Administrative* Code on the web site (http://www.sos.state.tx.us/tac).

For questions about the content and subject matter of rules, please contact the state agency that is reviewing the rules. Questions about the web site and printed copies of these notices may be directed to the *Texas Register* office.

Adopted Rule Reviews

Railroad Commission of Texas

Title 16, Part 1

The Railroad Commission of Texas (Commission) files this notice of completion of review and re-adoption of 16 TAC Chapter 14 relating to Regulations for Liquefied Natural Gas (LNG), with the exception of §14.2001, relating to LNG Advisory Committee, which is repealed in a separate, simultaneous rulemaking. This review and re-adoption has been conducted in accordance with Texas Government Code, §2001.039. The agency's reasons for adopting these rules, other than §14.2001, continue to exist. The Commission received no comments on the proposed review, which was published in the April 13, 2007, issue of the *Texas Register* (32 TexReg 2145).

Issued in Austin, Texas, on May 30, 2007.

TRD-200702120
Mary Ross McDonald
Managing Director
Railroad Commission of Texas
Filed: May 30, 2007

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State Securities Board

Title 7, Part 7

Pursuant to the notice of proposed rule review published in the *Texas Register* (32 TexReg 1101), March 2, 2007, the State Securities Board (Board) has reviewed and considered for readoption, revision, or repeal, all sections of the following chapters of Title 7, Part 7 of the Texas Administrative Code, in accordance with Texas Government Code, §2001.039: Chapter 113, Registration of Securities; Chapter 114, Federal Covered Securities; Chapter 123, Administrative Guidelines for Registration of Open-End Investment Companies; Chapter 125, Minimum Disclosures in Church and Nonprofit Institution Bond Issues; Chapter 135, Industrial Development Corporations and Authorities; and Chapter 137, Administrative Guidelines for Regulation of Offers.

The Board considered, among other things, whether the reasons for adoption of these rules continue to exist. After its review, the Board finds that the reasons for adopting these rules continue to exist and readopts these Chapters, without changes, pursuant to the requirements of the Government Code.

No comments were received regarding the readoption of Chapters 113, 114, 123, 125, 135, and 137.

This concludes the review of 7 TAC Chapters 113, 114, 123, 125, 135, and 137.

TRD-200702153
Denise Voigt Crawford
Securities Commissioner
State Securities Board
Filed: June 1, 2007

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Texas State Soil and Water Conservation Board

Title 31, Part 17

Pursuant to the notice of proposed rule review published in the March 23, 2007, issue of the *Texas Register* (32 TexReg 1753), the Texas State Soil and Water Conservation Board (State Board) has reviewed and considered for readoption, revision, or repeal 31 TAC, Part 17, Chapter 520, Subchapter A, §§520.1 - 520.6, Elections, in accordance with Texas Government Code, §2001.039.

The State Board considered, among other things, whether the reasons for adoption of these rules continue to exist. No comments were received on the proposed rule review.

As a result of the review, the State Board determined that the rules are still necessary and readopts, with change to the Chapter title, the sections since they govern the mandated election process for soil and water conservation districts.

TRD-200702238
Mel Davis
Special Projects Coordinator
Texas State Soil and Water Conservation Board
Filed: June 4, 2007

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TABLES & GRAPHICS

Graphic images included in rules are published separately in this tables and graphics section. Graphic images are arranged in this section in the following order: Title Number, Part Number, Chapter Number and Section Number.

Graphic images are indicated in the text of the emergency, proposed, and adopted rules by the following tag: the word "Figure" followed by the TAC citation, rule number, and the appropriate subsection, paragraph, subparagraph, and so on.

Figure: 16 TAC §18.12(e)

Table 1. Suggested Penalties for Violations of Chapter 18 and Penalty Calculation Worksheet.

Line no.	Conduct	Cite	Suggested Penalty	Amount
1	Failure to comply with Chapter 18	§18.1	$1,000	$
2	Failure to notify notification center	§18.3	$1,000	$
3	Failure to include method for positive response	§18.3	$1,000	$
4	Failure to use white lining where appropriate	§18.3	$1,000	$
5	Failure to conduct a required face-to-face meeting	§18.3	$1,000	$
6	Failure to establish protocols when required	§18.3	$1,000	$
7	Failure to give second notice when required	§18.4	$1,000	$
8	Failure to protect locate markings	§18.4	$1,000	$
9	Failure to wait the required time to dig	§18.4	$1,000	$
10	Failure to provide positive response on first or second call	§18.5	$1,000	$
11	Failure to keep record of positive response	§18.5	$1,000	$
12	Failure to notify of no positive response	§18.5; §18.11	$1,000	$
13	Failure to mark excavation or pipeline properly	§§18.6-18.8	$1,000	$
14	Failure to dig with care within Tolerance Zone	§18.10	$1,000	$
15	Failure of operator or excavator to report pipeline damage	§18.11	$1,000	$
16	Subtotal of penalty amounts (lines 1 through 15)			**$**
17	Reduction for settlement before hearing: up to 50% of line 16 amt.		%	$
18	**Subtotal (amount on line 17 less applicable settlement reduction on line 18)**			**$**
	Penalty enhancements	**Recommended Enhancement**		
19	Impact to a residential or public area	$5,000-$25,000		$
20	Reckless conduct of person charged	Double penalty amount		$
21	Second Offense	Double penalty amount		$
22	More than 2 but fewer than 5 violations	Triple Penalty amount		$
23	More than 5 but fewer than 10 violations	Four times Penalty amount		
24	More than 10 violations	Five times Penalty amount		$
25	**Subtotal (amount on line 18 plus all amounts on lines 19 through 24)**			**$**
26	Reduction for demonstrated good faith of person charged			$
27	**TOTAL PENALTY (amount on line 25 less any amount shown on line 26)**			**$**

Figure: 19 TAC §300.3(a)

TEXAS WORKFORCE COMMISSION
MEMORANDUM OF UNDERSTANDING
NONFINANCIAL AGREEMENT

TWC Contract Number **2907NFA006**

TITLE **Project Reintegration of Offenders (Project RIO)**

Party #1 Information

Name	**Texas Department of Criminal Justice**	Contact	**Brad Livingston**
Mailing Address	**PO Box 13084**	Contact Title	**Executive Director**
City/State/Zip	**Austin, TX 78778**	Telephone Number	**(512) 463-9776**

Party #2 Information

Name	**Texas Workforce Commission**	Contact	**Nicole Verver**
Mailing Address	**101 East 15th Street**	Contact Title	**Director, Workforce Policy**
City/State/Zip	**Austin, TX 78778**	Telephone Number	**(512) 936-3160**

Party #3 Information

Name	**Texas Youth Commission**	Contact	**Connie Simon**
Mailing Address	**PO Box 4260**	Contact Title	**Workforce Development Manager**
City/State/Zip	**Austin, TX 78765**	Telephone Number	**(512) 424-6091**

Party #4 Information

Name	**Windham School District**	Contact	**Bob Evans**
Mailing Address	**PO Box 40**	Contact Title	**Director, Continuing Education**
City/State/Zip	**Huntsville, TX 77342**	Telephone	**(936) 291-5179**

Agreement Period

Begin Date: **June 14, 2007** End Date: **August 31, 2010**

Purpose

To provide a delineation of responsibilities related to the administration and operation of Project RIO. This Non-Financial Agreement (Agreement) is developed with the intent to coincide with all contracts, strategic plans, policies, or agreements that affect the structure and scope of the Project RIO program.

Agreement Approval

This Agreement is contingent on all Parties' acceptance of and compliance with the terms and conditions of this Agreement and any referenced attachments.

Each person signing this Agreement on behalf of the Agency and the other Parties hereby warrants that he or she has been fully authorized by his or her organization to:

- **execute this agreement on behalf of the organization; and**
- **validly and legally bind the organization to all of the terms, performances, and provisions of this Agreement.**

Texas Department of Criminal Justice:

Brad Livingston, Executive Director Date
Texas Department of Criminal Justice

Texas Workforce Commission:

Larry E. Temple, Executive Director Date
Texas Workforce Commission

Texas Youth Commission:

Ed Owens, Interim Executive Director Date
Texas Youth Commission

Windham School District:

Debra Roberts, Superintendent Date
Windham School District

TEXAS WORKFORCE COMMISSION
MEMORANDUM OF UNDERSTANDING
AGREEMENT TERMS AND CONDITIONS

Table of Contents

GENERAL TERMS AND CONDITIONS

SECTION 1 - LEGAL AUTHORITY AND PARTIES

This Agreement is undertaken through the authority granted by the Interagency Cooperation Act (Section 771.001, et seq., Texas Government Code).

The Texas Department of Criminal Justice (TDCJ) manages offenders in state prisons, state jails, and private correctional facilities that contract with TDCJ. TDCJ also provides funding and certain oversight of community supervision (previously known as adult probation) and is responsible for the supervision of offenders released from prison on parole or mandatory supervision.

The Texas Workforce Commission (TWC) is responsible for administering an integrated workforce development system, including job training, employment, employment-related educational programs, and the Unemployment Insurance program, under the authority of Section 302.021, Texas Labor Code.

The Texas Youth Commission (TYC) is the state's juvenile corrections agency, providing for the care, custody, rehabilitation, and reestablishment in society of Texas' most chronically delinquent or serious juvenile offenders. Texas judges commit these youths to TYC mostly for felony-level offenses that occurred when the youths were at least age 10 and less than age 17. TYC can maintain jurisdiction over these offenders until their twenty-first birthdays.

The Windham School District's (WSD) mission is to provide appropriate educational programming and services to meet the needs of the eligible offender population in TDCJ and reduce recidivism by assisting offenders in becoming responsible, productive members of their communities.

SECTION 2 - PURPOSE

This Agreement sets forth the responsibilities and obligations of the signatory agencies with respect to the provision of Project RIO services. This Agreement is intended to address the requirements of Sections 306.004 and 306.005 of the Labor Code and Section 501.095 of the Government Code.

SECTION 3 - PERFORMANCE

All Parties agree to the provisions, performance, and commitments established within Attachment A - Statement of Work. Such performance shall be provided in compliance with:

- all applicable federal and state laws, regulations, and rules;
- all agency policies and procedures or guidance manuals incorporated within this Agreement herein by specific reference in Attachment A; and
- the terms and conditions of this Agreement.

All Parties agree that Confidentiality Agreements, as shown in Attachment B, will be executed as referenced in Section II (O) of Attachment A.

SECTION 4 - AMENDMENT AND TERMINATION

4.1 This Agreement, not withstanding Interagency Cooperation Contract, TWC #2907RIO000/TDCJ #69-6WS-7-7-A0128 and the local operating agreements referenced in Section V.B of Attachment A, is the entire agreement between the Parties, relating to the purpose stated in Section 2 of this Agreement. All oral or written agreements between the Parties hereto relating to the subject matter of this Agreement that were made prior to the execution of this Agreement have been reduced to writing and are contained herein.

4.2 Any alterations, additions, or deletions to the terms of this Agreement required by changes in federal or state law or by regulations are automatically incorporated into this Agreement without written amendment hereto, and shall become effective on the date designated by such law or regulation.

4.3 After a period of no less than 30 days subsequent to written notice (unless more rapid implementation is required by law), such formal directives shall have the effect of qualifying the terms of this Agreement and shall be binding upon all Parties as if written herein.

4.4 Except as specifically provided by Subsections 4.1, 4.2, and 4.3 of this Agreement, any additions, alterations, deletions, or extensions to the terms of this Agreement shall be by amendment hereto in writing and executed by all Parties to this Agreement. Any other attempted changes, including oral modifications, written notices that have not been signed by both Parties, or other modifications of any type, shall be invalid.

4.5 If at any time either Party is unable to perform its functions under this Agreement consistent with such Party's statutory and regulatory mandates, the affected Party shall immediately provide written notice to the other Parties to establish a date for resolution of issues.

4.6 The activities conducted pursuant to this Agreement shall be reviewed on a bi-annual basis and the Agreement adjusted as may be deemed appropriate by all signatories.

4.7 This Agreement may be terminated by 30 days written notice by any Party to all other Parties.

SECTION 5 - FINANCIAL

The Parties to this Agreement assume full responsibility for their respective costs associated with their performance of the terms of this Agreement. No property or other legal rights shall accrue or otherwise develop by virtue of the Parties entering into this Agreement.

ATTACHMENT A

STATEMENT OF WORK

I. TDCJ agrees to further the goals of Project RIO by:

A. TDCJ, Parole Division, shall:

1. administratively support the provision of Project RIO services through the Specialized Services section of the Parole Division, where policies and procedures supportive of the provision of Project RIO services shall be maintained;

2. assign Project RIO coordinators in each District Parole Office to act as points of contact for Texas Workforce Centers;

3. refer to Texas Workforce Centers all unemployed or underemployed parolees who are available for work, able to work, willing to seek employment, free of symptomatic evidence of substance abuse, free of outstanding warrants, and not in pre-revocation status.

4. monitor the participation of referred parolees to ensure that full use of available services is made;

5. provide parolee-specific information such as TDCJ commitment histories and employment restrictions to Texas Workforce Centers. Such efforts shall include data connectivity and elements stipulated in Section 306.008 of the Texas Labor Code;

6. distribute offender employment documents secured during incarceration by TDCJ-Criminal Institutions Division (CID) and the WSD where the point of release is the Gatesville or Huntsville Unit;

7. maintain and administer security agreements related to TDCJ access and use of The Workforce Information System of Texas (TWIST) and WorkInTexas.com; and

8. assist with the process for documenting and reporting if an ex-offender is placed in a job related to TDCJ training and employment retention.

B. TDCJ, Community Justice Assistance Division, shall:

1. encourage the referral of qualified offenders on community supervision to Project RIO, and ensure that those persons actively participate and fully avail themselves of the services available; and

2. educate local community supervision and corrections departments (CSCD) concerning the existence, eligibility criteria, and benefits of Project RIO services.

C. TDCJ, Manufacturing and Logistics (M&L) Division, shall:

1. provide a work program designed to provide offenders with marketable skills and work ethic. This undertaking will help reduce recidivism through a coordinated program of:

a. job skills training – Vocational completers of the WSD and/or local community colleges will be placed in M&L jobs as applicable to gain work experience in their trade of training. Offenders meeting program requirements shall also be enrolled in the Work Against Recidivism (WAR) program. Job skills training and related work experience shall be provided to all M&L program participants; and

b. documentation of work history – A WAR employment sheet shall be completed for each WAR program participant upon release to document job skills training, work history, and performance evaluation of the offender.

2. convey to TWC's TWIST automated system a data set reflecting participation in M&L and WAR services provided and other elements stipulated in Section 306.008 of the Texas Labor Code.

II. TWC agrees to further the goals of Project RIO by:

A. administratively supporting the provision of Project RIO service provision through TWC's Workforce Development Division and developing and maintaining policies governing service provision in Title 40, Texas Administrative Code, Chapter 847;

B. allocating available Project RIO resources to Local Workforce Development Boards (Boards) to support the provision of services to ex-offenders and adjudicated youth through Texas Workforce Centers;

C. supporting Texas Workforce Centers designed to provide employment and training services to ex-offenders and adjudicated youth who are:

1. adults who were sentenced to a TDCJ correctional facility and are:

a. within one year after their release from incarceration; or

b. currently under parole supervision by TDCJ, or within one year of completion of their term of supervision

2. adjudicated youth ages 16 through 21 who were formerly confined in a TYC correctional facility.

D. encouraging Boards to prioritize the referral of Project RIO customers to employment related to their skills, training, and/or experience acquired while incarcerated;

E. maintaining a system for continuance of services where a Project RIO customer has a need for post-employment support or where employment is secured in a job unrelated to training received during incarceration and/or the goals established in the Individual Employment Plan (IEP);

F. providing oversight, technical assistance, and support to Boards in furtherance of services to the eligible ex-offender and adjudicated youth populations;

G. maintaining previously established linkages and establishing new linkages with local service providers and resources, including faith based and community organizations;

H. providing training support to TDCJ, TYC, Boards, Texas Workforce Center personnel, and designated CSCD staff at designated local sites;

I. annually gathering and documenting follow-up information on a designated sample of participants in Project RIO;

J. coordinating joint efforts with staff from the various agencies in educating the public as to the goals, progress, and results of Project RIO;

K. coordinating and participating in the promotion of eligible ex-offenders' use of Project RIO;

L. providing reports and/or data access available through TWIST and WorkInTexas.com to TDCJ, TYC, and WSD reflecting the status of program participants and completers;

M. providing TDCJ and TYC staff and offenders with current information regarding the locations and services offered in Texas Workforce Centers;

N. assisting with the process for documenting and reporting if an ex-offender is placed in a job related to TDCJ or TYC training and employment retention;

O. ensuring that any information received from TYC regarding current or former TYC youth will be protected as confidential under Section 58.005 of the Texas Family Code. In furtherance of this assurance, TWC will require that all Texas Workforce Center staff accessing TYC information execute a Confidentiality Agreement. A copy of the Confidentiality Agreement is included as Attachment B to this Agreement; and

P. maintaining security agreements related to the release of criminal histories generated from the Criminal Justice Information System.

III. TYC shall further the goals of Project RIO by:

A. organizing and administering prerelease Project RIO services within the Education Department of the TYC's Rehabilitation Division. Policies and procedures for prerelease Project RIO services shall be established and maintained within TYC's Education Department. Project RIO staff located in secure facilities will be under the direct daily supervision of the TYC campus principals. Program Supervision is provided by TYC Central Office Workforce Development Programs staff.

B. stationing Project RIO staff in TYC-secure facilities, to the extent that resources permit, for the purpose of providing prerelease Project RIO services to adjudicated youth designed to equip them with the knowledge, skills, and attitudes necessary to successfully reintegrate into society and the labor market;

C. providing prerelease Project RIO services to adjudicated youth, ages 16-21, with appropriate security status, who elect to participate.

D. providing a TYC Project RIO institutional component concerned with the provision of reentry services to adjudicated youth. Service provision generally will be focused on the last six months of confinement and will include:

1. outreach, recruitment, and orientation of adjudicated youth;
2. assessment to determine academic and vocational interests, aptitudes, and needs;
3. workforce development counseling, career exploration, and the provision of labor market information specific to the adjudicated youths' reentry community;
4. development of an IEP detailing specific vocational goals and the academic and vocational training, work experience, and reentry elements to achieve goals;
5. referral to available work assignments or Prison Industry Enhancement (PIE) employment opportunities that further goals established in an adjudicated youth's IEP;
6. assistance in securing and compiling documents necessary to secure and retain employment to include such items as Texas Department of Public Safety driver license and identification cards, birth certificates, Social Security cards, and academic and vocational training certificates. Documents secured during confinement will be provided by TYC to an adjudicated youth at the point of release;
7. post-release referral of adjudicated youth who are in need of workforce services by TYC's Community Services Division.
8. exit interviews with releasing adjudicated youth to finalize reentry plans and ensure awareness and access to post-release Project RIO services;

E. providing a TYC Project RIO institutional component concerning the provision of academic and vocational assessment, workforce development counseling, and workforce development training services to adjudicated youth while committed to TYC facilities;

F. providing client-specific information such as offense histories and employment restrictions to Project RIO personnel, in accordance with existing Texas statutes and TYC administrative policies;

G. compiling and transmitting to TWC a data set reflecting the adjudicated youth's IEP, services provided during confinement, and parole referral information, as established by Section 306.008 of the Texas Labor Code;

H. promoting the use of post-release Project RIO services by adjudicated youth through orientation and information sessions conducted within the institutional component, as well as parole and transitional placement facilities;

I. maintaining and administering security agreements related to TYC access and use of TWIST and WorkInTexas.com;

J. referring by the TYC Parole Division of all unemployed or underemployed adjudicated youth who are under the supervision of the TYC;

K. monitoring adjudicated youths' Project RIO participation to ensure that full use is made of all of services; and

L. providing adjudicated youths with information regarding programs and services available through TWC and Texas Workforce Centers including the Work Opportunity Tax Credit and fidelity bonding.

IV. WSD agrees to further the goals of Project RIO by:

A. organizing and administering prerelease Project RIO services within WSD. Project RIO staff shall be under the direct daily supervision of unit WSD principals. Policies and procedures for prerelease Project RIO services shall be established and maintained within WSD's Continuing Education Division;

B. stationing Project RIO staff in CID facilities, to the extent that resources permit, for the purpose of providing prerelease Project RIO services to offenders designed to equip them with the knowledge, skills, and attitudes necessary to successfully reintegrate into society and the labor market;

C. providing Project RIO services to eligible offenders who elect to participate. Eligibility shall be based upon the following criteria:

1. Must have an appropriate offender classification status;
2. Must be willing to participate and work on assigned tasks to relieve barriers to employment, and any requirements listed on the Individual Treatment Plans:
3. Must plan to reside in the state of Texas;
4. Must not have a verified Immigration and Customs Enforcement (ICE) or felony detainer; and
5. Must be within appropriate priority levels as established by Project RIO program guidelines.

D. providing offenders with timely and appropriate reentry services, including:

1. outreach, recruitment, and orientation of offenders;
2. assessment activities to determine academic and occupational interest and aptitudes and work histories;
3. career exploration counseling and provision of labor market information specific to the offenders' reentry into the community;
4. development of an IEP detailing the specific academic and vocational training, work experience, and reentry elements necessary to achieve the offenders' occupational goals;
5. assisting offenders with completion of a WorkInTexas.com employment application;
6. referral and enrollment into academic, vocational, life skills, and behavioral training opportunities available through WSD and local community colleges and universities;
7. assistance in obtaining and compiling documents necessary to secure and retain employment, including such items as driver licenses, birth certificates, Social Security cards, DD214's, Selective Service, and academic and vocational training certificates;
8. career fairs to familiarize offenders with community resources, employer expectations and, where possible, in-unit employer recruitment;
9. quarterly interviews with participating offenders to case manage progress towards achieving IEP goals;

10. exit interviews with releasing offenders to finalize reentry plans and ensure awareness and access to post-release Project RIO services;
11. distribution of offenders' employment documents secured during incarceration, where the point of release is other than the Gatesville Unit or Huntsville Unit; and
12. conveying to TWC's TWIST automated system a data set reflecting prerelease services provided and other elements stipulated in Section 306.008 of the Texas Labor Code.

E. maintaining and administering security agreements related to WSD access and use of TWIST and WorkInTexas.com; and

F. providing offenders with information regarding programs and services available through TWC and the Texas Workforce Centers, including the Work Opportunity Tax Credit and Fidelity Bonding.

V. The Parties mutually agree to:

A. jointly pursue the goals, strategies, and action steps specified in the Project RIO Strategic Plan; and

B. facilitate the development of local operating agreements with Boards to implement this agreement.

ATTACHMENT B

CONFIDENTIALITY AGREEMENT RELATING TO RELEASE OF INFORMATION UNDER SECTION 58.005, TEXAS FAMILY CODE

STATE OF TEXAS) (
) (
COUNTY OF_____) (

AFFIDAVIT

Before me, the undersigned authority, personally appeared _____ known to me to be the person whose name is subscribed to the following instrument, and having been by me first duly sworn, upon his or her oath deposes and stated the following:

My name is _____. I am over the age of 18 and a resident of _____County, Texas. I am employed at _____my position _____.

I request that the following confidential information to be released to me by the Texas Youth Commission (TYC) pursuant to Texas Family Code Section 58.005(a)(5):

- Adjudication History
- Texas Youth Commission Records/Information related to Vocational and Educational Services
- Parole information relevant to securing employment and/or continuance of education

I certify that the requested information is to be used for treatment or services to TYC youth only.

I understand that the above-referenced information is confidential and that release of this information to me does not serve to waive or affect the confidentiality of the information for purposes of state or federal law or waive the right to assert exceptions to required disclosure of the information in the future.

The requested information may not be disclosed outside the requesting entity or within the requesting entity for purposes other than the purpose for which it was received. The information shall be marked "CONFIDENTIAL" and kept in a secure place.

Any copies of the information or any notes taken from the information that implicate the confidential nature of the information will be controlled, with all copies or notes that are not destroyed or returned to TYC remaining confidential and subject to the confidentiality agreement.

_____
Signature of Affiant

SWORN TO AND SUBSCRIBED before me on _____, 20 _____.

_____
Notary Public, State of Texas

My Commission Expires: _____

IN ADDITION

The *Texas Register* is required by statute to publish certain documents, including applications to purchase control of state banks, notices of rate ceilings issued by the Office of Consumer Credit Commissioner, and consultant proposal requests and awards. State agencies also may publish other notices of general interest as space permits.

Texas State Affordable Housing Corporation

Notice of Public Hearing

Regarding the Issuance of Bonds

Notice is hereby given of a public hearing to be held by the Texas State Affordable Housing Corporation (the "Issuer") at 12:00 p.m. on June 29, 2007 at 1005 Congress Avenue, Suite B-10 (Conference Room), Austin, Texas 78701, on the proposed issuance by the Issuer of one or more series of multifamily housing revenue bonds (the "Bonds") to provide financing for the following multifamily housing projects (collectively, the "Projects"):

1. Chaparral Village Apartments, 1411 S. Grant Street, City of Odessa, County of Ector, Texas, approximately 80 units; Owner: RHAC--Chaparral, LLC;

2. Cove Village Apartments, 1102 Golf Course Road, City of Copperas Cove, County of Coryell, Texas, approximately 50 units; Owner: RHAC--Cove, LLC;

3. El Nido Apartments, 204 Alicia Drive, City of El Paso, County of El Paso, Texas, approximately 104 units; Owner: RHAC--El Nido, LLC;

4. Garden Apartments, 1340 65th Drive, City of Lubbock, County of Lubbock, Texas, approximately 44 units; Owner: RHAC--Garden, LLC;

5. Garden Apartments, 6516 Avenue T, City of Lubbock, County of Lubbock, Texas, approximately 18 units; Owner: RHAC--Garden, LLC;

6. High Plains Apartments, 1607 Iola Avenue, City of Lubbock, County of Lubbock, Texas, approximately 50 units; Owner: RHAC--High Plains, LLC;

7. Jose Antonio Escajeda Apartments, 710 South Park, City of El Paso, County of El Paso, Texas, approximately 20 units; Owner: RHAC--JAE, LLC;

8. Jose Antonio Escajeda Apartments, 1010 South Tays, City of El Paso, County of El Paso, Texas, approximately 20 units; Owner: RHAC--JAE, LLC;

9. Jose Antonio Escajeda Apartments, 710 Father Rahm, City of El Paso, County of El Paso, Texas, approximately 4 units; Owner: RHAC--JAE, LLC;

10. Jose Antonio Escajeda Apartments, 710 S Tays, City of El Paso, County of El Paso, Texas, approximately 12 units; Owner: RHAC--JAE, LLC;

11. Jose Antonio Escajeda Apartments, 700 South Kansas/709 South Campbell, City of El Paso, County of El Paso, Texas, approximately 32 units; Owner: RHAC--JAE, LLC;

12. Los Ebanos Apartments, 2133 Barnard Road, City of Brownsville, County of Cameron, Texas, approximately 65 units; Owner: RHAC--Ebanos, LLC;

13. Peppertree Acres Apartments, 6555 Sheridan Circle, City of Fort Worth, County of Tarrant, Texas, approximately 44 units; Owner: RHAC--Peppertree, LLC;

14. Peppertree Acres Apartments, 1000 Oak Grove Court, City of Fort Worth, County of Tarrant, Texas, approximately 36 units; Owner: RHAC--Peppertree, LLC;

15. Peppertree Acres Apartments, 5200 Southcrest Court, City of Fort Worth, County of Tarrant, Texas, approximately 38 units; Owner: RHAC--Peppertree, LLC;

16. Peppertree Acres Apartments, 2300 Ephriham Court, City of Fort Worth, County of Tarrant, Texas, approximately 30 units; Owner: RHAC--Peppertree, LLC;

17. River Park Village East Apartments, 1309 Central Texas Expressway, City of Lampasas, County of Lampasas, Texas, approximately 50 units; Owner: RHAC--River Park, LLC;

18. Salem Village Apartments, 5201 John Stockbauer Drive, City of Victoria, County of Victoria, Texas, approximately 105 units; Owner: RHAC--Salem, LLC;

19. Sierra Vista Apartments, 10501 Montwood, City of El Paso, County of El Paso, Texas, approximately 106 units; Owner: by RHAC--Sierra, LLC;

20. Spring Terrace Apartments, 2600 S. Spring Street, City of Amarillo, County of Potter, Texas, approximately 50 units; Owner: RHAC--Spring, LLC; and

21. Win-Lin Village Apartments, 5700 Wabash Street, City of Amarillo, County of Potter, Texas, approximately 50 units; Owner: RHAC--WinLin, LLC.

The maximum aggregate face amount of the Bonds to be issued with respect to the Projects is $44,000,000. All interested persons are invited to attend the public hearing to express orally, or in writing, their views on the Projects and the issuance of the Bonds. The Bonds shall not constitute or create an indebtedness, general or specific, or liability of the State of Texas, or any political subdivision thereof. The Bonds shall never constitute or create a charge against the credit or taxing power of the State of Texas, or any political subdivision thereof. Neither the State of Texas, nor any political subdivision thereof shall in any manner be liable for the payment of the principal of or interest on the Bonds or for the performance of any agreement or pledge of any kind which may be undertaken by the Issuer and no breach by the Issuer of any agreements will create any obligation upon the State of Texas, or any political subdivision thereof. Further information with respect to the proposed Bonds will be available at the hearing or upon written request prior thereto addressed to the Issuer at 1005 Congress Avenue, Suite 500, Austin, Texas 78701, Attention: David W. Danenfelzer; 1-888-638-3555, extension 403.

Individuals who require auxiliary aids in order to attend this meeting should contact Laura Ross, ADA Responsible Employee, at 1-888-638-3555, extension 400 through Relay Texas at 1-800-735-2989 at least two days before the meeting so that appropriate arrangements can be made. Individuals who require child care to be provided at this meeting should contact Laura Ross at 1-888-638-3555, extension 400, at

least five days before the meeting so that appropriate arrangements can be made.

Individuals may transmit written testimony or comments regarding the subject matter of this public hearing to David Danenfelzer at ddanenfelzer@tsahc.org.

TRD-200702227
David Long
President
Texas State Affordable Housing Corporation
Filed: June 4, 2007

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Texas Department of Agriculture

Request for Qualifications: Bond and Program Counsel

1. Purpose.

The Texas Agricultural Finance Authority (the Authority), a public authority within the Texas Department of Agriculture (the Department), is seeking proposals in response to this Request for Qualifications (RFQ) for bond and program counsel. The Authority is seeking to employ Bond Counsel and Program Counsel to assist the Authority in the issuance of and/or purchase of bonds and to provide general program assistance when needed under Chapter 44, Chapter 58, and Chapter 59 of the Texas Agriculture Code (the Code).

2. Background of the Authority

The Authority was created by the Texas Legislature for the purpose of financing innovative, diversified, or value-added production, processing, marketing, or export businesses in Texas. The Authority can provide financing through instruments including direct loans, loan guaranties, insurance, or co-insurance. The Authority is governed by a nine-member Board of Directors (the Board), appointed by the Governor with the consent of the State Senate for two-year staggered terms. Employees of the Department are designated by the Commissioner of Agriculture to administer the Authority.

The Board may approve eligible borrowers for financing through direct loans, loan guaranties, loan participation, direct issuance of obligations, or other financial instruments. The Authority may also purchase bonds or municipal anticipation notes from eligible local government entities for the purpose of assisting those local government entities in their rural economic development efforts.

Chapter 58 and Chapter 59 of the Code also provide for the issuance by the Authority of revenue bonds and general obligation bonds. Under Chapter 58 of the Code, the Authority is authorized to issue up to $230 million in general obligation bonds and up to $500 million in revenue bonds for rural agricultural development and agricultural-related projects in the state of Texas. Under Chapter 59 of the Code, the Authority may issue up to $300 million of general obligation bonds for financing agricultural real estate.

3. Statement of Duties for the Counsel.

The counsel's responsibilities for bond work will include, but will not be limited to, advice to the Board and staff of the Department (Staff) on: the legal ramifications and constraints of the issuance and investment policy; the legality of loan policy proposals and legal aspects of investments and loan policy; the legality of proposed debt structuring techniques; compliance with federal tax and securities requirements for financings associated with the Authority's programs; real and anticipated changes in state and federal law, regulations, or public policy; and the potential and real impact on existing or anticipated bond issues, investment policy, and loan policy.

With respect to new bond issues, Bond Counsel, in consultation with the Authority's Financial Advisor and Staff, may be asked to prepare or review legal documents required by the Board, Comptroller of Public Accounts, Office of the Attorney General, or outside parties; request and obtain approval of the bond issue from the Office of the Attorney General, Governor, Bond Review Board, and other required authorities; and review all financial models and render opinions on the legality and relevant tax position of the proposed issuance and lending scenario.

The counsel shall also perform such other legal services, if requested by the Authority, that do not come within the functions of Bond Counsel for a particular bond issue, but are needed for the implementation and administration of the programs of the Authority. Such services shall include, without limitation, the following: consultation concerning planning and development of programs of the Authority; providing advice concerning policies for lending or granting funds to eligible borrowers; review of program applications; review and drafting of loan documents; assistance in implementing loan guarantee programs; advice and services concerning legislation affecting such programs; advising on, and upon request of the Authority, initiating and pursuing collection actions in relation to loan programs; and providing advice concerning administration of the Authority.

4. Proposal Contents.

Responses to this RFQ should include, at least, the following: a thorough description of your firm's ability to represent the Authority in the stated job duties; a description of your firm's past experience as counsel for other state agencies; a description of your firm's past experience as counsel to state and federal banks, credit unions, finance companies, and other financial institutions; a designation of the individuals who might be assigned to the work of the Authority; examples of similar programs in which your firm has assisted as legal counsel; a quotation of your proposed fee structure based upon the issuance of financing enhanced by the general obligation of the State and/or a stand alone revenue bond issuance; a statement addressing the effort made by your firm to encourage and develop the participation of women and minorities in your firm; affirmation that the firm does not, and shall not during the term of the contract, represent any plaintiff in a proceeding seeking monetary damages from the State of Texas or any of its agencies; and a statement of willingness to comply with policies, directives, and guidelines of the Authority and the Attorney General of the State of Texas.

5. Statement of Evaluation Process.

Responses to this RFQ will be evaluated and ranked according to the information provided and summarized for the Board's review. Staff will rank the proposals and make a recommendation to the Board at the first available meeting. The Board intends to select the proposal that demonstrates the highest degree of competency and the necessary qualifications and experience in providing the requested legal services at a fair and reasonable price. The Authority reserves the right to contract with separate Bond and Program Counsel, and to contract with more than one Bond or Program Counsel.

6. Proposal Requirements.

A duly authorized representative of the firm must execute the submitted response. An unsigned response will not be accepted. Issuance of this RFQ in no way constitutes a commitment by the Authority to award a contract, to issue bonds, or to pay for any services incurred either in the preparation of a response to this RFQ or for the production of any contract for services. The Authority also reserves the right to make amendments to the qualifications requested by giving written notice to all firms who receive this RFQ. All communications with the Authority concerning this RFQ and the selection of Bond Counsel or Program Counsel shall be directed to Rick Rhodes, Assistant Commissioner for Rural Economic Development, with the Department, acting

as program manager on behalf of the Authority. Any contact by a submitting firm, its employees, or representatives with any Board member of the Authority for the purposes of soliciting or encouraging a favorable review may be considered grounds for disqualification.

7. Proposal Submission.

All proposals must be received no later than 5:00 p.m., August 1, 2007. Proposal responses, modifications, or addenda to an original response received by the Authority after the specified time and date for closing will not be considered. Each firm is responsible for ensuring that its response reaches the Authority before the proposed due date. Firms should submit one (1) unbound original and three (3) copies of their proposal to: Mr. Rick Rhodes, Assistant Commissioner for Rural Economic Development, Texas Agricultural Finance Authority, c/o Texas Department of Agriculture, P.O. Box 12847, Austin, Texas 78711, Street Address: 1700 N. Congress Ave., Stephen F. Austin Bldg., 11th Floor, Austin, Texas 78701.

Please mark the envelopes containing proposals with the following note in the lower left-hand corner: **IN RESPONSE TO PROPOSAL REQUEST: BOND and PROGRAM COUNSEL**. All proposals become the property of the Authority. Proposals must set forth full, accurate, and complete information as required by this request. Oral responses, instructions, or offers will not be considered. The Authority reserves the right to reject any and all responses.

8. Term of the Agreement.

The contract term shall be for the period beginning September 1, 2007, through August 31, 2008.

9. Terms of the Agreement.

The contract issued under this RFQ will be in the form prescribed by the Office of the Attorney General for Outside Counsel Contracts.

10. Proposal Modification.

Any response may be modified or withdrawn even after received by the Authority at any time prior to the proposal due date. No material changes will be allowed after the expiration of the proposal due date; however, non-substantive corrections or deletions may be made with the approval of Staff. The Authority reserves the exclusive right to review proposals and make an appropriate selection from such proposals. The Authority is not bound to accept any proposal by virtue of this RFQ.

11. Cost Incurred In Responding.

All costs directly or indirectly related to preparation of a response to the RFQ or any oral presentation required to supplement and/or clarify the RFQ which may be required by the Authority shall be the sole responsibility of, and shall be borne by, your firm.

12. Release Of Information And Open Records.

All proposals shall be deemed, once submitted, to be the property of the Authority and are subject to the Texas Public Information Act (the Act). Under the Act, information submitted in response to this RFQ may not be released by the Authority during the proposal evaluation process or prior to the awarding of a contract. After the Authority completes the process and a contract is awarded, proposals and information included therein may be subject to public disclosure under the Act.

TRD-200702276
Dolores Alvarado Hibbs
General Counsel
Texas Department of Agriculture
Filed: June 6, 2007

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Office of the Attorney General

Notice of Settlement of a Texas Clean Air Act Enforcement Action

Notice is hereby given by the State of Texas of the following proposed resolution of an environmental enforcement lawsuit under the Texas Clean Air Act. Before the State may settle a judicial enforcement action, pursuant to the Texas Water Code, the State shall permit the public to comment in writing on the proposed judgment. The Attorney General will consider any written comments and may withdraw or withhold consent to the proposed agreed judgment if the comments disclose facts or considerations that indicate that the consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act.

Case Title and Court: Settlement Agreement in Harris County, Texas and the Texas Commission on Environmental Quality v. Columbia Environmental Services; Cause No. 2006-40042, 234th Judicial District, Harris County, Texas.

Background: This suit alleges violations of the Texas Clean Air Act resulting from the improper use of a trench burner in Harris County, Texas. The Defendant is Columbia Environmental Services. The suit seeks injunctive relief, civil penalties, attorney's fees and court costs. The Clean Air Act violations are for air pollution and air nuisance.

Nature of Settlement: The settlement awards $6,250.00 in civil penalties and $1,000.00 in attorney's fees to the State and $6,250.00 in civil penalties and $1,500.00 in attorney's fees to Harris County. The settlement also prohibits the Defendants from operating a trench burner in the State of Texas.

For a complete description of the proposed settlement, the complete proposed Interlocutory Agreed Final Judgments that will comprise the Agreed Final Judgment should be reviewed. Requests for copies of the judgments, and written comments on the proposed settlement should be directed to Vanessa Puig-Williams, Assistant Attorney General, Office of the Texas Attorney General, P.O. Box 12548, Austin, Texas 78711-2548, (512) 463-2012, facsimile (512) 320-0052. Written comments must be received within 30 days of publication of this notice to be considered.

TRD-200702132
Stacey Napier
Deputy Attorney General
Office of the Attorney General
Filed: June 1, 2007

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Coastal Coordination Council

Notice and Opportunity to Comment on Requests for Consistency Agreement/Concurrence Under the Texas Coastal Management Program

On January 10, 1997, the State of Texas received federal approval of the Coastal Management Program (CMP) (62 Federal Register pp. 1439-1440). Under federal law, federal agency activities and actions affecting the Texas coastal zone must be consistent with the CMP goals and policies identified in 31 TAC Chapter 501. Requests for federal consistency review were deemed administratively complete for the following project(s) during the period of May 25, 2007, through May 31, 2007. As required by federal law, the public is given an opportunity to comment on the consistency of proposed activities in the coastal zone undertaken or authorized by federal agencies. Pursuant to 31 TAC §§506.25, 506.32, and 506.41, the public comment period for this ac-

tivity extends 30 days from the date published on the Coastal Coordination Council web site. The notice was published on the web site on June 6, 2007. The public comment period for this project will close at 5:00 p.m. on July 6, 2007.

FEDERAL AGENCY ACTIONS:

Applicant: Calhoun County Navigation District; Location: The project is located in the Matagorda Ship Channel (MSC), Calhoun and Matagorda Counties, Texas. The proposed project site extends from the existing Calhoun County Navigation District (CCND) berthing facilities at the Port of Port Lavaca-Point Comfort, through Lavaca Bay and Matagorda Bay, and ending offshore in the Gulf of Mexico. The project can be located on the U.S. Geological Survey quadrangle maps entitled Decros Point, Port O'Connor, Seadrift NE, Carancahua Pass, Keller Bay, Port Lavaca East, Turtle Bay, Olivia, and Point Comfort, Texas. Project Description: The CCND proposes to deepen their berthing facilities at the Port of Port Lavaca-Point Comfort (Port), enlarge the approximately 26.6-mile-long MSC from the existing turning basin at the Port (Channel Station 117+223), through Lavaca Bay and Matagorda Bay, and ending offshore in the Gulf of Mexico (Channel Station -23+000). A proposed new turning basin at the intersection of the MSC and the Alcoa Channel would have a 1,650-foot turning circle, and the existing CCND berthing facilities, the existing and proposed turning basins, and a proposed new CCND berthing area adjacent to the proposed new turning basin would be dredged to a depth of -44 feet Mean Low Tide (MLT). The authorized channel dimensions of the MSC, from the Port to the Matagorda Peninsula, are 200 feet wide (bottom width) by -36 feet MLT deep, and the CCND proposes to enlarge this reach to 400 feet wide by -44 feet MLT deep (plus 2 feet of advanced maintenance depth and 2 feet of overdepth). The existing authorized channel dimensions through the Matagorda Peninsula are 300 feet wide by -36 feet MLT deep, and the CCND proposes to enlarge this reach to 600 feet wide by -46 feet MLT deep (plus 3 feet of advanced maintenance and 2 feet of overdepth). In the Gulf of Mexico, the existing authorized channel dimensions are 300 feet wide by -38 feet MLT deep, and CCND proposes to enlarge the offshore reach to 600 feet wide by -46 feet MLT deep (plus 3 feet of advanced maintenance and 2 feet of overdepth). The CCND proposes to use both hydraulic and mechanical dredges, including hopper dredges, to perform new work and maintenance dredging of the proposed project. Approximately 46.5 million cubic yards of new work dredged material would be generated from the proposed widening and deepening project. Maintenance dredging of the proposed channel would generate approximately 257.5 million cubic yards of material during the 50-year planning period. Dredged material would be used to create or protect habitats, nourish beaches, and cap mercury-impacted sediments, and would be placed in confined dredged material placement areas (DMPA's) in bays and on land, and in unconfined DMPA's in Matagorda Bay and in unconfined ocean dredged material disposal sites (ODMDS) in the Gulf of Mexico. Additional dredging and placement of 400,000 cubic yards of dredged material would create a levee designed to protect habitat. CCC Project No.: 07-0190-F1; Type of Application: U.S.A.C.E. permit application #24071 is being evaluated under §10 of the Rivers and Harbors Act of 1899 (33 U.S.C.A. §403), §404 of the Clean Water Act (33 U.S.C.A. §1344), and §103 of the Marine Protection, Research and Sanctuaries Act (33 U.S.C.A. §1401). Note: The consistency review for this project may be conducted by the Texas Commission on Environmental Quality under §401 of the Clean Water Act (33 U.S.C.A. §1344).

Applicant: Save Cedar Bayou, Inc.; Location: The project cannot be accessed by automobile. It is located on St. Joseph Island approximately 10 miles northeast of Rockport on the San Patricio/Aransas County Line between the Aransas National Wildlife Refuge and the San Jose Cattle Company Ranch. It is an approximately 2.52-linear-mile-long dredging project involving two channels that would connect Cedar Bayou and Vinson Slough with the Gulf of Mexico. The project can be located on the U.S.G.S. quadrangle map entitled: Saint Charles Bay SE, Texas. Approximate UTM Coordinates in NAD 27 (meters): The Cedar Bayou Channel would begin at approximately Zone 14; Easting: 711680; Northing: 3107715 and end in the Gulf of Mexico at approximately Zone 14; Easting: 711200; Northing: 3105790. The Vinson Slough Channel would begin at approximately Zone 14; Easting: 709620; Northing: 3106400; head southeast and turn almost due east at Zone 14; Easting: 710240; Northing: 3105980. It would then make a northeasterly turn at Zone 14; Easting: 710620; Northing: 3105990 where it would join the Cedar Bayou Channel at Zone 14; Easting: 711396; Northing: 3106593. Project Description: The proposed Cedar Bayou/Vinson Slough Habitat Restoration Project is a dredging project designed to reconnect Aransas Bay with the Gulf of Mexico (GOM) by re-opening Cedar Bayou. The purpose of this project is to restore and maintain the hydraulic connection between these two bodies of water by establishing a persistent hydraulic connection between Vinson Slough and Cedar Bayou at their confluence with the GOM and restore an ebb delta at the mouth of the Cedar Bayou. The applicant expects that the ebb delta will minimize sediment deposition at the mouth of the pass by allowing sediment to bypass across it. The Cedar Bayou and Vinson Slough proposed channels are not intended for navigational purposes.

To maintain the pass as an open channel the applicant proposes to excavate approximately 503,350 cubic yards of material from approximately 58.5 acres of Cedar Bayou and Vinson Slough. The material to be excavated has been identified by a geotechnical investigation as beach-quality sand with a median grain size diameter of approximately 0.15mm and a silt and clay content of no more than 5%. The 58.5-acre area is composed of 47.5 acres and 454,850 cubic yards in waters of the United States and 11.0 acres and 48,500 cubic yards from placement area that was used during a 1995 Cedar Bayou dredging event. The applicant proposes to dredge a straight channel along the easternmost 6,175 feet (approximate) of the existing Cedar Bayou Channel to the GOM. Dredging in this channel would involve the removal of 175,050 cubic yards of material from 21 acres. The other portion of the dredging operation involves the removal of approximately 279, 800 cubic yards of material from 26.5 acres to form and an angular 7115-foot channel in Vinson Slough so that it connects with the Cedar Bayou Channel before the Cedar Bayou Channel reaches the GOM. The proposed dimensions for both the Cedar Bayou and Vinson Slough Channels are 100 feet wide (bottom cut) by 6 feet deep (-5.62 feet NAVD 88) with 4H:1V side slopes. The applicant expects that the slopes of the newly dredged channel will not differ from the existing slopes, which vary from 100H:1V to 3H:1V, once hydrodynamic forces bring the channels into equilibrium.

The excavated material would be placed in two different areas near the project site. Approximately 48,500 cubic yards of material from the 1995 placement area would be used to re-nourish the beach along 18.5 acres of the upper beach approximately 3,400 feet south of the proposed channel mouth. This material will be moved using land-based earth-moving equipment and placed in the inter-tidal area along the beach. The construction template will have a berm height of +6 feet NAVD88 starting at the seaward edge of the exiting dune feature. The material will not be placed on existing vegetation. The berm width would be approximately 200 feet, terminating in a 20H:1V seaward slope down to the existing sea bottom.

The approximately 454,850 cubic yards of material would be hydraulically dredged during the channel excavation and placed offshore of the mouth to create two ebb deltas on either side of the mouth of the pass. During construction of these deltas, the maximum elevation of placed sand would not exceed +2.0 feet NAVD88. The shape of the

construction template will be modified in plan view and cross-section through coastal processes. It is expected that the constructed template will rapidly transform into a submerged delta.

The construction template has a 100-foot crest width constructed to +2 feet NAVD88 with side slopes of 20H:1V to 30H:1V depending on the wave conditions during and after material placement. The northeast delta, Delta A, is approximately 2,930 feet long and contains 304,800 cubic yards placed over approximately 41 acres. The southwest delta, Delta B, is approximately 2,100 feet long and contains approximately 150,050 cubic yards placed over approximately 26 acres. The project does not propose to create emergent features in the Gulf of Mexico or turn submerged lands in to uplands.

The applicant reports that the purpose of the proposed ebb delta is to reduce wave setup at the mouth of the Bayou by pushing the location of wave breaking farther offshore. Hydrologic modeling suggests that the deltas should help to minimize the resistance to the flow out of Cedar Bayou. In addition, the applicant's models indicate that the delta will cause increased wave breaking along its seaward side and will redirect longshore sediment transport along the seaward side of the delta instead of along the Cedar Bayou shoreline, in effect bypassing the longshore sediment transport seaward of the mouth.

The applicant reports that, from their interpretation of aerial photography along the proposed channel alignment, the alignment is configured to prevent impacts to submerged vegetation and adjacent wetlands along the channel banks; however, the alignment area and the areas adjacent to it have not been surveyed for the presence or absence of submerged and emergent vegetation. It is anticipated that dredging will be conducted with a hydraulic cutterhead-type dredge and/or employ a mechanical dredging technique. The applicant proposes to conduct construction activities beginning after April 15 of the calendar year wherein work commences and will be completed prior to October 15 in order to avoid the whooping crane wintering season (October 15th to April 15th). It would not be possible to construct the project outside of the turtle nesting season (March 15th to September 30th) due to the whooping crane nesting window. Therefore, the applicant proposes to implement a turtle monitoring plan prior to and during beach construction activities. CCC Project No.: 07-0192-F1; Type of Application: U.S.A.C.E. permit application #SWG-2007-813 is being evaluated under §10 of the Rivers and Harbors Act of 1899 (33 U.S.C.A. §403) and §404 of the Clean Water Act (33 U.S.C.A. §1344). Note: The consistency review for this project may be conducted by the Texas Commission on Environmental Quality under §401 of the Clean Water Act (33 U.S.C.A. §1344).

Applicant: Boss Operating Company; Location: The project is located in Matagorda Bay, in State Tract (ST) 150, south of Caracahua Bay, in Calhoun County, Texas. The project can be located on the U.S.G.S. quadrangle map entitled: Carancahua Pass, Texas. Approximate UTM Coordinates in NAD 27 (meters) of existing ST 150, Well No. 1: Zone 14; Easting: 757651; Northing: 3163412. Approximate UTM Coordinates in NAD 27 (meters) of existing ST 150, Well No. 2: Zone 14; Easting: 757437; Northing: 3163449. Approximate UTM Coordinates in NAD 27 (meters) of proposed ST 150, Well No. 3: Zone 14; Easting: 757416; Northing: 3163449. Project Description: The applicant proposes to install, operate and maintain structures and equipment necessary for oil and gas drilling, production and transportation activities for ST 150, Well No. 3. Such activities include installation of typical marine barges and keyways, production structures with attendant facilities. The applicant proposes to move 3,800 cubic yards of shell and gravel from their ST 150, Well No. 1, site, to the proposed ST 150, Well No. 3 site, to create a shell pad for the drilling barge.

The applicant proposes to install a 70-foot-long flowline from ST 150, Well No. 3, to ST 150, Well No. 2, and a 793-foot flowline from ST 150, Well No. 2, to ST 150, Well No. 1. The applicant proposes to use an existing access channel, previously permitted under permit 23439, to access the well sites. Depth at the project site is -12 feet below mean lower low water. CCC Project No.: 07-0194-F1; Type of Application: U.S.A.C.E. permit application #23439(01) is being evaluated under §10 of the Rivers and Harbors Act of 1899 (33 U.S.C.A. §403) and §404 of the Clean Water Act (33 U.S.C.A. §1344). Note: The consistency review for this project may be conducted by the Railroad Commission of Texas under §401 of the Clean Water Act (33 U.S.C.A. §1344).

Applicant: Hall-Houston Exploration II, LP; Location: The project is located in Gulf of Mexico, Federal waters, Galveston Area Block 312 in the Freeport Anchorage Area, offshore, Texas. The State Plane, Texas South Central Coordinates in NAD 27 (feet) are X=3228945.81; Y=383280.00. Project Description: The applicant proposes to drill one well from the aforementioned surface location. A typical jack-up rig would be utilized and, if producible, a 4-pile production platform would be installed. CCC Project No.: 07-0198-F1; Type of Application: U.S.A.C.E. permit application #SWG-2007-820 is being evaluated under §10 of the Rivers and Harbors Act of 1899 (33 U.S.C.A. §403).

Applicant: Plains Exploration and Production Company; Location: The project is located approximately 18 miles SE from Port O'Connor in OCS Block 557 of the Matagorda Island Area within the Matagorda Anchorage Area, offshore Federal waters, Texas. The State Plane, Texas South Central Coordinates in NAD 83 (feet) are X=2868658.92; Y=173654.75. Project Description: The applicant proposes to install, operate and maintain a typical jack-up rig, production platform and/or well protector, with appurtenant structures and equipment necessary to conduct oil and gas drilling/production operations. CCC Project No.: 07-0199-F1; Type of Application: U.S.A.C.E. permit application #SWG-2007-656 is being evaluated under §10 of the Rivers and Harbors Act of 1899 (33 U.S.C.A. §403).

Pursuant to §306(d)(14) of the Coastal Zone Management Act of 1972 (16 U.S.C.A. §§1451-1464), as amended, interested parties are invited to submit comments on whether a proposed action is or is not consistent with the Texas Coastal Management Program goals and policies and whether the action should be referred to the Coastal Coordination Council for review.

Further information on the applications listed above may be obtained from Ms. Tammy Brooks, Consistency Review Coordinator, Coastal Coordination Council, P.O. Box 12873, Austin, Texas 78711-2873, or tammy.brooks@glo.state.tx.us. Comments should be sent to Ms. Brooks at the above address or by fax at (512) 475-0680.

TRD-200702262
Larry L. Laine
Chief Clerk/Deputy Land Commissioner, General Land Office
Coastal Coordination Council
Filed: June 6, 2007

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Comptroller of Public Accounts

Notice of Contract Award

Pursuant to §1201.027, Texas Government Code; Chapter 2254, Subchapter B, Texas Government Code; and Chapter 404, Subchapter H, Texas Government Code, the Comptroller of Public Accounts (Comptroller) announces the award of the following contract:

A contract is awarded to RBC Capital Markets 2711 North Haskell, Suite 2400, Dallas, Texas 75204-2936. The total contract amount for the contract is a $37,775 fee and $6,500 in expenses for each Tax Rev-

enue Anticipation Note issue during the term of the contract. The term of the contract is May 30, 2007 through August 31, 2009.

The Comptroller's Request for Proposals #178a related to this contract award was published in the March 9, 2007, issue of the *Texas Register* (32 TexReg 1385).

TRD-200702228
Pamela G. Smith
Deputy General Counsel for Contracts
Comptroller of Public Accounts
Filed: June 4, 2007

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Notice of Request for Proposals

Pursuant to §§403.011, 2155.001, and 2156.121, Texas Government Code, and Chapter 54, Subchapters F and G, Texas Education Code, the Comptroller of Public Accounts (Comptroller) on behalf of the Texas Prepaid Higher Education Tuition Board (Board) announces its Request for Proposals (RFP No. 178e) for Domestic Core Fixed-Income Investment Management Services (Services) in connection with the administration of the prepaid higher education tuition program. The funds to be managed are funds from contracts and investments of the program known as the Texas Tomorrow Funds (Program). The Comptroller and Board request proposals for the Services for the Program. If approved by the Board, the successful respondent(s), if any, will be expected to begin performance of the contract on or about September 1, 2007, or as soon thereafter as practical.

Contact: Parties interested in submitting a proposal should contact William Clay Harris, Assistant General Counsel, Contracts, Comptroller of Public Accounts, 111 E. 17th St., Room G-24, Austin, Texas 78774, (512) 305-8673, to obtain a complete copy of the RFP. The Comptroller will mail copies of the RFP only to those parties specifically requesting a copy. The RFP will be available for pick-up at the above referenced address on Friday, June 15, 2007, after 10:00 a.m. Central Zone Time (CZT), and during normal business hours thereafter. The Comptroller will also make the entire RFP available electronically on the Electronic State Business Daily (ESBD) after 10:00 a.m. on Friday, June 15, 2007. The website address is http://esbd.tbpc.state.tx.us

Questions and Non-Mandatory Letters of Intent: All written inquiries, questions, and non-mandatory Letters of Intent to propose must be received at the above-referenced address not later than 2:00 p.m. (CZT) on Friday, June 29, 2007. Respondents are encouraged to fax Non-Mandatory Letters of Intent and Questions to (512) 463-3669 to ensure timely receipt. The Letter of Intent must be addressed to William Clay Harris, Assistant General Counsel, Contracts, and must contain the information as stated in the corresponding Section of the RFP and be signed by an official of that entity. On or before Friday, July 6, 2007, the Comptroller expects to post responses to questions as a revision to the electronic notice of the issuance of the RFP. Late Non-mandatory Letters of Intent and Questions received after the deadline will not be considered; all respondents are solely responsible for ensuring timely receipt of Questions and Letters of Intent in the Issuing Office.

Closing Date: Proposals must be delivered to the Office of the Assistant General Counsel, Contracts, at the location specified above (in ROOM G24) no later than 2:00 p.m. (CZT), on Friday, July 13, 2007. Late proposals received after this time and date will not be considered; all respondents are solely responsible for ensuring timely receipt of proposals in the Issuing Office.

Evaluation Criteria: Proposals will be evaluated under the evaluation criteria outlined in the RFP. The Board makes the final decision on award(s). The Comptroller and the Board each reserve the right to accept or reject any or all proposals submitted. The Comptroller and the Board are not obligated to execute a contract on the basis of this notice or the distribution of any RFP. The Comptroller and the Board shall not pay for any costs incurred by any entity in responding to this Notice or the RFP.

The anticipated schedule of events pertaining to this solicitation is as follows: Issuance of RFP - Friday, June 15, 2007, after 10:00 a.m. CZT; Non-Mandatory Letters of Intent & Questions Due - June 29, 2007, 2:00 p.m. CZT; Official Responses to Questions posted - July 6, 2007; Proposals Due - July 13, 2007, 2:00 p.m. CZT; Contract Execution - August 31, 2007, or as soon thereafter as practical; Services Available under Contract - September 1, 2007.

TRD-200702263
Pamela G. Smith
Deputy General Counsel for Contracts
Comptroller of Public Accounts
Filed: June 6, 2007

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Request for Letter Proposals for Outside Counsel Services

Pursuant to Chapters 403 and 404 of the Texas Government Code, the Texas Treasury Safekeeping Trust Company (Trust Company), through the Comptroller of Public Accounts (Comptroller), issues this Request for Letter Proposals (RFP) from local, qualified, independent law firms with offices in Austin to serve as outside counsel to the Trust Company, a statutory, special-purpose trust company. The individual attorney or attorneys primarily responsible for and performing the legal services required by the Trust Company must be based in the Austin office. Under this RFP, the Trust Company shall select qualified counsel to provide the Trust Company with legal services on an as-needed basis in a variety of general civil matters requiring expertise generally in banking, partnership, corporate, business, finance, federal taxation, contracts, administrative, securities and investments law and practice; and must have significant practice in and experience with alternative investments, including but not limited to, hedge, private equity and real estate funds (Alternative Investments). The Trust Company expects to evaluate respondents and make a contract award no later than August 31, 2007. Respondents must be able to begin providing services on an as-needed basis immediately and throughout the contract term currently expected to be September 1, 2007 through August 31, 2008, with two (2) additional options to renew, at the Trust Company's sole option, for one (1) year periods exercised one (1) year at a time but which may be changed at the discretion of the Trust Company.

Questions and Proposed Contract: Questions concerning this RFP and requests for copies of the proposed sample contract must be in writing and submitted via hand delivery or facsimile no later than Friday, June 29, 2007, 2:00pm, Central Zone Time (CZT) to William Clay Harris, Assistant General Counsel, Contracts, Comptroller of Public Accounts, 111 E. 17th St., ROOM G-24, Austin, Texas 78774, telephone number: (512) 305-8673, facsimile (512) 463-3669 (Issuing Office). The Trust Company's official response to questions received by this deadline will be posted as an addendum to this Texas Marketplace notice on Friday, July 6, 2007, or as soon thereafter as practical. A copy of the proposed contract will be provided upon request.

Closing Date: An original and five (5) copies of each Letter Proposal must be hand delivered to and received in the Issuing Office at the address specified above no later than 2:00 p.m. (CZT), on Friday, July 20, 2007. Proposals received after this date and time will not be considered. Respondents shall be solely responsible for confirming the timely receipt of proposals.

Content: Letter Proposals must include all of the following information in order to be considered:

1. Transmittal letter that (a) describes specific experience and qualifications of both the law firm (Law Firm) and each proposed partner and associate in each of the requisite areas of practice, specifically highlighting recent experience in representing governmental entities like the Trust Company in similar matters, particularly with respect to the governmental entity investing in Alternative Investments; and (b) outlines Law Firm's understanding of the Trust Company's enabling legislation, other legislation applicable to the Trust Company, and the funds the Trust Company manages;

2. Physical address of Law Firm's Austin offices;

3. Vita for each proposed partner and associate;

4. Proposed hourly rates for each proposed partner and associate and statements as to (a) whether proposed fees are negotiable; (b) how proposed fees compare to recently contracted fees with other governmental entities on similar matters; (c) proposed reimbursement basis for out-of-pocket expenses other than travel; and (d) whether proposed fees are firm throughout expected initial contract term (September 1, 2007 through August 31, 2008);

5. Proposed mechanisms to control and communicate regarding total costs, such as providing the Trust Company with estimates of billable costs prior to beginning specific assignments and timely advising the Trust Company when additional work is required to complete those assignments;

6. Disclosures of conflicts of interest (identifying each and every matter in which the Law Firm has, within the past calendar year, represented any entity or individual with an interest adverse to the Trust Company, Comptroller, or the State of Texas, or any of its boards, agencies, commissions, universities, or elected or appointed officials);

7. Information regarding efforts made by the Law Firm to encourage and develop the participation of minorities and women in the provision of services such as those requested by this RFP; and

8. Confirmation of willingness to comply with the policies, directives and guidelines of the Trust Company and the Attorney General of the State of Texas.

Evaluation and Award Procedure: All qualifying Letter Proposals received by the deadline above will be evaluated based on qualifications, experience and reasonableness of proposed fees. The Trust Company will make the final selection in its sole discretion in the best interests of the Trust Company and the State of Texas. Notice of contract award will be published on the Texas Marketplace and the Texas Register as soon as possible after execution of the contract.

Limitations: The Trust Company reserves the right to accept or reject any or all Letter Proposals submitted in response to this RFP. The Trust Company is not obligated to execute any contract as a result of issuing this RFP. The Trust Company shall pay no costs or any other amounts incurred by any entity in responding to this RFP. The selected Law Firm's sole compensation shall be limited to contracted amounts in the final negotiated contract. No minimum amount of work or assignments under any resulting contract is guaranteed. No travel expenses will be paid by the Trust Company unless expressly and previously approved by the Trust Company. The Trust Company may solicit or select other legal counsel to provide the same or similar services at any time.

Summary of Schedule: The anticipated schedule, subject to change by the Trust Company, is as follows: Publication of RFP in *Texas Register* - Friday, June 15, 2007; Posting of RFP on Texas Marketplace - Friday, June 15, 2007; Questions and Requests for Copies of Sample Contract Due - Friday, June 29, 2007, 2:00 p.m. CZT; Official Responses to Questions Posted - Friday, July 6, 2007; Proposals Due - Friday, July 20, 2007, 2:00 p.m. CZT; Contract Execution - September 1, 2007, or as soon thereafter as practical; Services Available- September 1, 2007, or as soon thereafter as practical.

TRD-200702264
Pamela G. Smith
Deputy General Counsel for Contracts
Comptroller of Public Accounts
Filed: June 6, 2007

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Office of Consumer Credit Commissioner

Notice of Rate Ceilings

The Consumer Credit Commissioner of Texas has ascertained the following rate ceilings by use of the formulas and methods described in §303.003 and §303.009, Texas Finance Code.

The weekly ceiling as prescribed by §303.003 and §303.009 for the period of 06/11/07 - 06/17/07 is 18% for Consumer[1]/Agricultural/Commercial[2]/credit through $250,000.

The weekly ceiling as prescribed by §303.003 and §303.009 for the period of 06/11/07 - 06/17/07 is 18% for Commercial over $250,000.

[1]Credit for personal, family or household use.

[2]Credit for business, commercial, investment or other similar purpose.

TRD-200702246
Leslie L. Pettijohn
Commissioner
Office of Consumer Credit Commissioner
Filed: June 5, 2007

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Texas Commission on Environmental Quality

Agreed Orders

The Texas Commission on Environmental Quality (TCEQ or commission) staff is providing an opportunity for written public comment on the listed Agreed Orders (AOs) in accordance with Texas Water Code (the Code), §7.075. Section 7.075 requires that before the commission may approve the AOs, the commission shall allow the public an opportunity to submit written comments on the proposed AOs. Section 7.075 requires that notice of the proposed orders and the opportunity to comment must be published in the *Texas Register* no later than the 30th day before the date on which the public comment period closes, which in this case is **July 16, 2007**. Section 7.075 also requires that the commission promptly consider any written comments received and that the commission may withdraw or withhold approval of an AO if a comment discloses facts or considerations that indicate that consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the statutes and rules within the commission's jurisdiction or the commission's orders and permits issued in accordance with the commission's regulatory authority. Additional notice of changes to a proposed AO is not required to be published if those changes are made in response to written comments.

A copy of each proposed AO is available for public inspection at both the commission's central office, located at 12100 Park 35 Circle, Building C, 1st Floor, Austin, Texas 78753, (512) 239-1864 and at the applicable regional office listed as follows. Written comments about an AO should be sent to the enforcement coordinator designated for each AO at the commission's central office at P.O. Box 13087, Austin, Texas 78711-3087 and must be **received by 5:00 p.m. on July 16, 2007**.

Written comments may also be sent by facsimile machine to the enforcement coordinator at (512) 239-2550. The commission enforcement coordinators are available to discuss the AOs and/or the comment procedure at the listed phone numbers; however, §7.075 provides that comments on the AOs shall be submitted to the commission in **writing**.

(1) COMPANY: Air Liquide Large Industries U.S. LP; DOCKET NUMBER: 2007-0206-AIR-E; IDENTIFIER: RN100215334; LOCATION: Freeport, Brazoria County, Texas; TYPE OF FACILITY: industrial gas manufacturing plant; RULE VIOLATED: 30 Texas Administrative Code (TAC) §101.201(a)(1)(B) and Texas Health and Safety Code (THSC), §382.085(b), by failing to notify the commission of a reportable emission event; 30 TAC §101.20(1) and (3) and §101.221(a), 40 Code of Federal Regulations (CFR) §60.18(c)(2), Permit Number 32274/PSD-TX-955M1/N-042, Special Condition Number 9(A) and 9(B), and THSC, §382.085(b), by failing to properly operate emission control equipment; and 30 TAC §101.20(3) and §116.115(c), Permit Number 32274/PSD-TX-955M1/N-042, Special Condition Number 1, and THSC, §382.085(b), by failing to maintain carbon monoxide emissions; PENALTY: $6,681; ENFORCEMENT COORDINATOR: Lindsey Jones, (512) 239-4930; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

(2) COMPANY: BASF Corporation; DOCKET NUMBER: 2007-0247-AIR-E; IDENTIFIER: RN100218049; LOCATION: Freeport, Brazoria County, Texas; TYPE OF FACILITY: chemical manufacturing plant; RULE VIOLATED: 30 TAC §116.115(b)(2)(F) and (c), New Source Review (NSR) Permit Number 1733A, Special Condition 1, and THSC, §382.085(b), by failing to prevent unauthorized emissions; and 30 TAC §116.115(c), NSR Permit Number 9513A, Special Condition 1, and THSC, §382.085(b), by failing to prevent unauthorized emissions; PENALTY: $18,100; ENFORCEMENT COORDINATOR: Trina Grieco, (210) 490-3096; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

(3) COMPANY: City of Brownsboro; DOCKET NUMBER: 2004-0077-MWD-E; IDENTIFIER: RN101721025, Texas Pollutant Discharge Elimination System (TPDES) Permit Number 10540-001; LOCATION: Henderson County, Texas; TYPE OF FACILITY: wastewater treatment; RULE VIOLATED: 30 TAC §305.125(1), TPDES Permit Number 10540-001, and the Code, §26.121(a), by failing to meet its permitted effluent limitations; PENALTY: $6,730; ENFORCEMENT COORDINATOR: Michael Meyer, (512) 239-4492; REGIONAL OFFICE: 2916 Teague Drive, Tyler, Texas 75701-3756, (903) 535-5100.

(4) COMPANY: Serena Cartwright; DOCKET NUMBER: 2007-0402-LII-E; IDENTIFIER: RN105124531; LOCATION: Wimberley, Hays County, Texas; TYPE OF FACILITY: landscaping business; RULE VIOLATED: 30 TAC §30.5(b) and §344.4(a), Texas Occupations Code, §1903.251, and the Code, §37.003, by failing to refrain from advertising or representing herself to the public as a person who can perform services for which a license or registration is required; PENALTY: $262; ENFORCEMENT COORDINATOR: Rajesh Acharya, (512) 239-0577; REGIONAL OFFICE: 2800 South IH 35, Suite 100, Austin, Texas 78704-5712, (512) 339-2929.

(5) COMPANY: Charleys Concrete Co., Ltd.; DOCKET NUMBER: 2007-0448-IWD-E; IDENTIFIER: RN100809268; LOCATION: Justin, Denton County, Texas; TYPE OF FACILITY: wastewater treatment; RULE VIOLATED: 30 TAC §305.125(1), General Permit Number TXG110353, Numeric Effluent Limitations, and the Code, §26.121(a), by failing to comply with permit effluent limits; PENALTY: $2,500; ENFORCEMENT COORDINATOR: Jorge Ibarra, (817) 588-5800; REGIONAL OFFICE: 2301 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(6) COMPANY: Imran Charolia; DOCKET NUMBER: 2005-0889-PST-E; IDENTIFIER: RN101192136; LOCATION: Harris County, Texas; TYPE OF FACILITY: convenience store with retail sales of gasoline; RULE VIOLATED: 30 TAC §334.50(b)(1)(A) and the Code, §26.3475(c)(1), by failing to monitor underground storage tanks (USTs) for releases; 30 TAC §334.50(b)(2) and the Code, §26.3475(a), by failing to provide proper release detection; 30 TAC §334.50(b)(2)(A)(i)(III) and the Code, §26.3475(a), by failing to test a line leak detector; 30 TAC §334.49(c)(2)(C) and the Code, §26.3475(d), by failing to have the impressed current cathodic protection system regularly inspected; 30 TAC §334.49(c)(4) and the Code, §26.3475(d), by failing to have the cathodic protection system tested by a qualified corrosion specialist or corrosion technician; 30 TAC §115.246(7)(A) and THSC, §382.085(b), by failing to maintain records on-site at facilities ordinarily manned during business hours, and make immediately available for review; 30 TAC §115.246(4) and THSC, §382.085(b), by failing to maintain proof of attendance and completion of training and documentation of all Stage II (SII) training for each employee; 30 TAC §115.246(6) and THSC, §382.085(b), by failing to maintain a daily inspection log; 30 TAC §115.245(2) and THSC, §382.085(b), by failing to verify proper operation of the SII equipment; 30 TAC §115.242(3)(A) and THSC, §382.085(b), by failing to maintain all components of the SII system in proper operating condition; and 30 TAC §334.22(a) and the Code, §5.702, by failing to pay UST registration fees; PENALTY: $7,875; ENFORCEMENT COORDINATOR: Trina Grieco, (210) 490-3096; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

(7) COMPANY: Chemicals Incorporated; DOCKET NUMBER: 2007-0590-IWD-E; IDENTIFIER: RN102145257; LOCATION: Mont Belvieu, Chambers County, Texas; TYPE OF FACILITY: organic chemical manufacturing and processing; RULE VIOLATED: 30 TAC §305.125(1), TPDES Permit Number WQ0003713000, Effluent Limitations and Monitoring Requirement Number 1, and the Code, §26.121(a), by failing to comply with permitted effluent limitations; PENALTY: $2,780; ENFORCEMENT COORDINATOR: Craig Fleming, (512) 239-5806; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

(8) COMPANY: Chevron Phillips Chemical Company LP; DOCKET NUMBER: 2007-0380-AIR-E; IDENTIFIER: RN102018322; LOCATION: Pasadena, Harris County, Texas; TYPE OF FACILITY: chemical manufacturing plant; RULE VIOLATED: 30 TAC §§101.20(1), 101.221(a), and 116.115(c), NSR Permit Number 5562A, Special Conditions 1 and 4, 40 CFR §60.18(c)(2), and THSC, §382.085(b), by failing to operate the flare with a pilot flame lit at all times and maintain an emission rate below the allowable emission limits; PENALTY: $4,275; ENFORCEMENT COORDINATOR: Jason Kemp, (512) 239-5610; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

(9) COMPANY: Contractor's Supplies, Inc.; DOCKET NUMBER: 2007-0622-IWD-E; IDENTIFIER: RN100250034, RN100249556; LOCATION: Harrison and Gregg Counties, Texas; TYPE OF FACILITY: ready-mixed concrete plants; RULE VIOLATED: 30 TAC §305.125(1), General Permit Numbers 110319 and 110197, Permit Requirements, and the Code, §26.121(a), by failing to comply with the permitted effluent limits for Facility 1 and 2; PENALTY: $4,380; ENFORCEMENT COORDINATOR: Cari-Michel LaCaille, (512) 239-1387; REGIONAL OFFICE: 2916 Teague Drive, Tyler, Texas 75701-3756, (903) 535-5100.

(10) COMPANY: Cottonwood Auction Barn, L.L.C.; DOCKET NUMBER: 2007-0556-AGR-E; IDENTIFIER: RN102900818; LOCATION: Erath County, Texas; TYPE OF FACILITY: auction barn; RULE VIOLATED: 30 TAC §321.42(s), by failing to develop and operate under a comprehensive nutrient management plan (CNMP) certified by the Texas State Soil and Water Conservation Board (TSSWCB); PENALTY: $1,840; ENFORCEMENT COORDINATOR: Lynley Doyen, (512) 239-1364; REGIONAL OFFICE: 2301 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(11) COMPANY: DCP Midstream, LP; DOCKET NUMBER: 2007-0200-AIR-E; IDENTIFIER: RN100218684; LOCATION: Andrews County, Texas; TYPE OF FACILITY: natural gas processing plant; RULE VIOLATED: 30 TAC §116.115(b)(2)(F) and (c), Federal Operating Permit (FOP) O-02566, Special Terms and Conditions No. 6, NSR Permit 2211A, Special Condition Number 1, and THSC, §382.085(b), by failing to maintain compliance with maximum allowable emission rate limits; PENALTY: $2,100; ENFORCEMENT COORDINATOR: Jessica Rhodes, (512) 239-2879; REGIONAL OFFICE: 3300 North A Street, Building 4, Suite 107, Midland, Texas 79705-5404, (915) 570-1359.

(12) COMPANY: E.I. du Pont de Nemours and Company; DOCKET NUMBER: 2007-0155-IHW-E; IDENTIFIER: RN100216035; LOCATION: Nederland, Jefferson County, Texas; TYPE OF FACILITY: petrochemical plant; RULE VIOLATED: 30 TAC §335.4 and the Code, §26.121(a), by failing to prevent the discharge of industrial hazardous waste; PENALTY: $136,400; ENFORCEMENT COORDINATOR: Colin Barth, (512) 239-0086; REGIONAL OFFICE: 3870 Eastex Freeway, Beaumont, Texas 77703-1892, (409) 898-3838.

(13) COMPANY: City of Hamilton; DOCKET NUMBER: 2007-0307-PWS-E; IDENTIFIER: RN101383586; LOCATION: Hamilton County, Texas; TYPE OF FACILITY: public water supply; RULE VIOLATED: 30 TAC §290.42(d)(2)(E), by failing to provide a proper air gap connection on the filter-to-waste connection; 30 TAC §290.42(f)(2)(F), by failing to locate the dry chemical feeders in a separate room that is provided with facilities for dust control; 30 TAC §290.45(b)(2)(B) and THSC, §341.0315(c), by failing to provide a minimum treatment plant capacity of 0.6 gallons per minute per connection; and 30 TAC §290.42(e)(4)(B), by failing to provide proper housing for the gas chlorine cylinders; PENALTY: $3,266; Supplemental Environmental Project (SEP) offset amount of $3,266 applied to Texas Association of Resource Conservation and Development Areas, Inc. ("RC&D")--Wastewater Treatment Assistance; ENFORCEMENT COORDINATOR: Christopher Miller, (512) 239-6580; REGIONAL OFFICE: 6801 Sanger Avenue, Suite 2500, Waco, Texas 76710-7826, (254) 751-0335.

(14) COMPANY: Daniel Potter dba Herbert's Auto Repair; DOCKET NUMBER: 2007-0240-PST-E; IDENTIFIER: RN100574441; LOCATION: Burleson, Johnson County, Texas; TYPE OF FACILITY: automotive repair; RULE VIOLATED: 30 TAC §334.51(b)(2)(C) and the Code, §26.3475(c)(2), by failing to equip the tank with a valve or other device designed to automatically shut off the flow of regulated substances into the tank when the liquid level in the tank reaches a preset level no higher than 95% capacity; 30 TAC §334.50(a)(1)(A) and the Code, §26.3475(c)(1), by failing to have a release detection method capable of detecting a release; and 30 TAC §37.815(a) and (b), by failing to demonstrate acceptable financial assurance; PENALTY: $4,500; ENFORCEMENT COORDINATOR: Shontay Wilcher, (512) 239-2136; REGIONAL OFFICE: 2301 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(15) COMPANY: Highway 46, LTD.; DOCKET NUMBER: 2007-0546-EAQ-E; IDENTIFIER: RN105186480; LOCATION: Bulverde, Comal County, Texas; TYPE OF FACILITY: property; RULE VIOLATED: 30 TAC §213.23(h), by failing to re-apply and receive approval for a Contributing Zone Plan; PENALTY: $1,000; ENFORCEMENT COORDINATOR: Cari-Michel LaCaille, (512) 239-1387; REGIONAL OFFICE: 14250 Judson Road, San Antonio, Texas 78233-4480, (210) 490-3096.

(16) COMPANY: Nancy Lea Huckabee and Linda Dianne Griffith dba Huckabee Dairy; DOCKET NUMBER: 2007-0508-AGR-E; IDENTIFIER: RN102708096; LOCATION: Hamilton County, Texas; TYPE OF FACILITY: dairy; RULE VIOLATED: 30 TAC §321.42(s), by failing to develop and operate under a CNMP certified by the TSSWCB; and 30 TAC §321.40(1) and TPDES Registration Number WQ0003699000, Section V, Conditions of the Registration, by failing to design, construct, and operate waste control facilities to manage contaminated rainfall runoff from open lots and associated areas; PENALTY: $2,225; ENFORCEMENT COORDINATOR: Lynley Doyen, (512) 239-1364; REGIONAL OFFICE: 6801 Sanger Avenue, Suite 2500, Waco, Texas 76710-7826, (254) 751-0335.

(17) COMPANY: Michael Jansky dba Jansky's Sand & Gravel; DOCKET NUMBER: 2007-0156-WQ-E; IDENTIFIER: RN101926046; LOCATION: Hallettsville, Lavaca County, Texas; TYPE OF FACILITY: sand and gravel operator; RULE VIOLATED: 30 TAC §281.25(a)(4) and 40 CFR §122.26(c), by failing to obtain authorization to discharge storm water associated with industrial activities; PENALTY: $2,100; ENFORCEMENT COORDINATOR: Ruben Soto, (512) 239-4571; REGIONAL OFFICE: 6300 Ocean Drive, Suite 1200, Corpus Christi, Texas 78412-5503, (361) 825-3100.

(18) COMPANY: City of Junction; DOCKET NUMBER: 2006-1802-MWD-E; IDENTIFIER: RN101920288; LOCATION: Junction, Kimble County, Texas; TYPE OF FACILITY: lift station; RULE VIOLATED: 30 TAC §305.125(1), TPDES Permit Number 10199001, Permit Conditions No. 2.g., and the Code, §26.121(a), by failing to prevent an unauthorized discharge of approximately 1,000 gallons of raw sewage from the collection system; and 30 TAC §317.3(e)(5), by failing to provide an operational audiovisual alarm at the lift station; PENALTY: $11,550; Supplemental Environmental Project (SEP) offset amount of $9,240 applied to holding two citywide collection events in which citizens may bring in tires, electronics, household hazardous waste, and large municipal solid waste for disposal at no cost to the citizens; ENFORCEMENT COORDINATOR: Amy Martin, (512) 239-2540; REGIONAL OFFICE: 622 South Oakes, Suite K, San Angelo, Texas 76903-7013, (915) 655-9479.

(19) COMPANY: Katy Independent School District; DOCKET NUMBER: 2007-0199-MWD-E; IDENTIFIER: RN101524973; LOCATION: Katy, Harris County, Texas; TYPE OF FACILITY: wastewater treatment; RULE VIOLATED: 30 TAC §305.125(1), TPDES Permit Number 12110001, Effluent Limitations and Monitoring Requirements Numbers 1 and 6, and the Code, §26.121(a), by failing to comply with permit effluent limits; PENALTY: $3,140; Supplemental Environmental Project (SEP) offset amount of $2,512 applied to Houston-Galveston AERCO's Clean Cities/Clean Vehicles Program; ENFORCEMENT COORDINATOR: Heather Brister, (512) 239-1203; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

(20) COMPANY: Kevin Dugas dba KH Dugas Construction/Demolition; DOCKET NUMBER: 2007-0268-MSW-E; IDENTIFIER: RN105120745; LOCATION: Beaumont, Jefferson County, Texas; TYPE OF FACILITY: construction/demolition debris removal company; RULE VIOLATED: 30 TAC §330.15(c), by failing to prevent the transportation of municipal solid waste for disposal at an unauthorized facility; PENALTY: $7,500; ENFORCEMENT COORDINATOR: Alison Echlin, (512) 239-3308; REGIONAL OFFICE: 3870 Eastex Freeway, Beaumont, Texas 77703-1892, (409) 898-3838.

(21) COMPANY: Kotexan, Inc. dba U.S. One Stop Food Mart; DOCKET NUMBER: 2007-0457-PST-E; IDENTIFIER: RN102230992; LOCATION: Dallas, Dallas County, Texas; TYPE OF FACILITY: convenience store with retail sales of gasoline; RULE VIOLATED: 30 TAC §334.49(c)(4) and the Code, §26.3475(d), by failing to have the cathodic protection system inspected and tested for operability and adequacy of protection; 30 TAC §334.50(b)(1)(A) and the Code, §26.3475(c)(1), by failing to ensure that all USTs are monitored in a manner which will detect a release; 30 TAC §334.50(b)(2) and the Code, §26.3475(a), by failing to conduct proper release detection; and 30 TAC §334.50(d)(1)(B)(ii) and the Code, §26.3475(c)(1), by failing to conduct reconciliation of detailed inventory control records; PENALTY: $5,100; ENFORCEMENT COORDINATOR: Judy Kluge, (817) 588-5800; REGIONAL OFFICE: 2301 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(22) COMPANY: LGI Land, Ltd.; DOCKET NUMBER: 2007-0446-WR-E; IDENTIFIER: RN104841085; LOCATION: Altoga, Collin County, Texas; TYPE OF FACILITY: land development business; RULE VIOLATED: 30 TAC §297.11 and the Code, §11.121, by failing to obtain a permit from the commission authorizing the appropriation of state water prior to pumping state water from a reservoir on Stiff Creek to use for commercial construction and land development purposes; PENALTY: $10,499; ENFORCEMENT COORDINATOR: Rebecca Clausewitz, (210) 490-3096; REGIONAL OFFICE: 2301 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(23) COMPANY: Loadcraft Industries, Ltd.; DOCKET NUMBER: 2006-2021-MLM-E; IDENTIFIER: RN101620748; LOCATION: Brady, McCulloch County, Texas; TYPE OF FACILITY: trailer and oil rig manufacturing; RULE VIOLATED: 30 TAC §116.110(a) and THSC, §382.085(b) and §382.0518(a), by failing to obtain authorization prior to construction and operation of a facility which emits air contaminants in the state; 30 TAC §106.452(1)(A) and THSC, §382.085(b), by failing to evacuate particulate matter emissions through a fabric filter; 30 TAC §106.8(c) and §106.433(8) and THSC, §382.085(b), by failing to comply with the general recordkeeping requirements; 30 TAC §106.433(2)(C) and §335.262(c)(1), (c)(2)(A), and (c)(2)(F) and 40 CFR §273.35(c), by failing to close universal waste containers after adding or removing waste and failure to label and mark the accumulation date on universal waste containers; 30 TAC §335.62 and 40 CFR §262.11, by failing to conduct a hazardous waste determination; 30 TAC §335.69(f)(4) and 40 CFR §262.34(d)(4), by failing to label a hazardous waste container with the accumulation start date and the words "hazardous waste;" 30 TAC §335.262(c)(3) and 40 CFR §265.176, by failing to manage universal waste at a distance greater than 50 feet from the property line; 30 TAC §335.6(c), by failing to update the plant's notice of registration; 30 TAC §335.9(a)(2), by failing to submit a correct annual waste summary; and 30 TAC §335.4, by failing to properly handle, store, and dispose of industrial solid waste; PENALTY: $43,028; Supplemental Environmental Project (SEP) offset amount of $17,211 applied to Texas Association of Resource Conservation and Development Areas, Inc. ("RC&D")--Unauthorized Trash Dump Clean-Up; ENFORCEMENT COORDINATOR: Dana Shuler, (512) 239-2505; REGIONAL OFFICE: 622 South Oakes, Suite K, San Angelo, Texas 76903-7013, (915) 655-9479.

(24) COMPANY: M & H Crates, Inc.; DOCKET NUMBER: 2005-0965-AIR-E; IDENTIFIER: RN101947919; LOCATION: Jacksonville, Cherokee County, Texas; TYPE OF FACILITY: crate and pallet manufacturing; RULE VIOLATED: 30 TAC §111.201 and THSC, §382.085(b), by allegedly having conducted unauthorized outdoor burning of waste wood products for disposal purposes; PENALTY: $1,050; ENFORCEMENT COORDINATOR: Harvey Wilson, (512) 239-0321; REGIONAL OFFICE: 2916 Teague Drive, Tyler, Texas 75701-3756, (903) 535-5100.

(25) COMPANY: Memorial Point Utility District; DOCKET NUMBER: 2007-0300-MWD-E; IDENTIFIER: RN102806866; LOCATION: Polk County, Texas; TYPE OF FACILITY: wastewater treatment; RULE VIOLATED: 30 TAC §305.125(1), Permit Number WQ0011147001, Effluent Limitations and Monitoring Requirements, and the Code, §26.121(a), by failing to comply with permit effluent limits; PENALTY: $3,340; Supplemental Environmental Project (SEP) offset amount of $2,672 applied to Texas Association of Resource Conservation and Development Areas, Inc. ("RC&D")--Unauthorized Trash Dump Clean-Up; ENFORCEMENT COORDINATOR: Harvey Wilson, (512) 239-0321; REGIONAL OFFICE: 3870 Eastex Freeway, Beaumont, Texas 77703-1892, (409) 898-3838.

(26) COMPANY: Phillip Mercado; DOCKET NUMBER: 2007-0224-MSW-E; IDENTIFIER: RN105119432; LOCATION: Mission, Hidalgo County, Texas; TYPE OF FACILITY: unauthorized municipal solid waste disposal site; RULE VIOLATED: 30 TAC §330.15(c), by failing to prevent the unauthorized disposal of municipal solid waste; PENALTY: $11,250; ENFORCEMENT COORDINATOR: Clinton Sims, (512) 239-6933; REGIONAL OFFICE: 1804 West Jefferson Avenue, Harlingen, Texas 78550-5247, (956) 425-6010.

(27) COMPANY: Naz Stores Inc. dba Tully Food Mart; DOCKET NUMBER: 2007-0375-PST-E; IDENTIFIER: RN101892768; LOCATION: Houston, Harris County, Texas; TYPE OF FACILITY: convenience store with retail sales of gasoline; RULE VIOLATED: 30 TAC §115.242(3) and THSC, §382.085(b), by failing to maintain the Stage II vapor recovery system (VRS) in proper operating condition and free of defects; 30 TAC §334.50(a)(1)(A) and the Code, §26.3475(c)(1), by failing to have a release detection method capable of detecting a release from any portion of the UST system; 30 TAC §334.50(d)(4)(A)(iii)(II) and the Code, §26.3475(c)(1), by failing to perform an automatic test for substance loss that can detect a release; 30 TAC §334.8(c)(5)(B)(ii), by failing to timely renew a previously issued UST delivery certificate by submitting a properly completed UST registration and self-certification form; and 30 TAC §334.8(c)(5)(A)(i) and the Code, §26.3467(a), by failing to make available to a common carrier a valid, current TCEQ delivery certificate; PENALTY: $4,500; ENFORCEMENT COORDINATOR: Rajesh Acharya, (512) 239-0577; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

(28) COMPANY: North Milam Water Supply Corporation; DOCKET NUMBER: 2007-0309-MLM-E; IDENTIFIER: RN102681889; LOCATION: Milam County, Texas; TYPE OF FACILITY: public water supply; RULE VIOLATED: 30 TAC §290.41(c)(3)(O) and §290.43(e), by failing to provide a properly constructed intruder-resistant fence; 30 TAC §290.43(c)(2), by failing to provide the roof hatch with a gasket to form a positive seal; 30 TAC §290.42(e)(4)(A), by failing to provide a bottle of fresh ammonia solution for testing for chlorine leakage; 30 TAC §290.42(l), by failing to maintain a facility operations manual for operator review and reference; 30 TAC §290.46(f)(2), by failing to provide water system records for review at the time of the investigation; 30 TAC §290.41(c)(1)(F), by failing to provide a sanitary control easement or an approved exception to the easement requirement that covers the land within 150 feet of the water system's well; and 30 TAC §290.42(i) and the Code, §26.121(a), by failing to obtain a permit from the commission prior to any discharge of wastewater; PENALTY: $4,266; Supplemental Environmental Project (SEP) offset amount of $3,413 applied to Texas Association of Resource Conservation and Development Areas, Inc. ("RC&D")--Abandoned Tire Clean-Up; ENFORCEMENT COORDINATOR: Yuliya Dunaway, (210) 490-3096;

REGIONAL OFFICE: 6801 Sanger Avenue, Suite 2500, Waco, Texas 76710-7826, (254) 751-0335.

(29) COMPANY: Ron Stuard dba Pecos River Crossing; DOCKET NUMBER: 2007-0205-PST-E; IDENTIFIER: RN103762605; LOCATION: Sheffield, Pecos County, Texas; TYPE OF FACILITY: convenience store with retail sales of gasoline; RULE VIOLATED: 30 TAC §334.50(b)(2) and the Code, §26.3475(a), by failing to conduct proper release detection; and 30 TAC §334.50(b)(2)(A)(i)(III) and the Code, §26.3475(a), by failing to test the line leak detectors; PENALTY: $2,250; ENFORCEMENT COORDINATOR: Thomas Greimel, (512) 239-5690; REGIONAL OFFICE: 3300 North A Street, Building 4, Suite 107, Midland, Texas 79705-5404, (915) 570-1359.

(30) COMPANY: Tim Peters; DOCKET NUMBER: 2007-0270-LII-E; IDENTIFIER: RN104859822; LOCATION: Houston and Katy, Harris County, Texas; TYPE OF FACILITY: lawn maintenance and landscape business; RULE VIOLATED: 30 TAC §30.5(a) and §344.4, Texas Occupations Code, §1903.251, and the Code, §37.003, by failing to possess an irrigator license; PENALTY: $625; ENFORCEMENT COORDINATOR: Libby Hogue, (512) 239-1165; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

(31) COMPANY: Plains Pipeline, L.P.; DOCKET NUMBER: 2007-0523-AIR-E; IDENTIFIER: RN100216712; LOCATION: Wood County, Texas; TYPE OF FACILITY: natural gas compression plant; RULE VIOLATED: 30 TAC §122.146(2), FOP Number O-02669, Special Terms and Conditions Number 5, and THSC, §382.085(b), by failing to submit compliance with the terms and conditions of FOP No. O-02669; PENALTY: $2,000; ENFORCEMENT COORDINATOR: Jessica Rhodes, (512) 239-2879; REGIONAL OFFICE: 2916 Teague Drive, Tyler, Texas 75701-3756, (903) 535-5100.

(32) COMPANY: Southwest Tire Disposal, LLC; DOCKET NUMBER: 2007-0186-MSW-E; IDENTIFIER: RN105153738; LOCATION: Odessa, Ector County, Texas; TYPE OF FACILITY: unauthorized scrap tire storage; RULE VIOLATED: 30 TAC §328.60(a), by failing to obtain a scrap tire storage site registration; PENALTY: $2,500; ENFORCEMENT COORDINATOR: Clinton Sims, (512) 239-6933; REGIONAL OFFICE: 3300 North A Street, Building 4, Suite 107, Midland, Texas 79705-5404, (915) 570-1359.

(33) COMPANY: The Goodyear Tire & Rubber Company; DOCKET NUMBER: 2007-0337-AIR-E; IDENTIFIER: RN100870898; LOCATION: Houston, Harris County, Texas; TYPE OF FACILITY: synthetic rubber manufacturing plant; RULE VIOLATED: 30 TAC §116.715(a), Flexible Air Permit Number 6618, Special Condition 1, and THSC, §382.085(b), by failing to prevent unauthorized emissions; 30 TAC §101.201(a) and THSC, §382.085(b), by failing to properly notify the TCEQ of an emissions event; PENALTY: $11,856; Supplemental Environmental Project (SEP) offset amount of $4,742 applied to Houston-Galveston AERCO's Clean Cities/Clean Vehicles Program; ENFORCEMENT COORDINATOR: Kimbery Morales, (713) 767-3500; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

(34) COMPANY: Town of Ponder; DOCKET NUMBER: 2007-0289-MWD-E; IDENTIFIER: RN102739349; LOCATION: Denton County, Texas; TYPE OF FACILITY: wastewater treatment; RULE VIOLATED: 30 TAC §305.125(1), TPDES Permit Number 11287003, Effluent Limitations and Monitoring Requirements Number 1 and 2, and the Code, §26.121(a), by failing to comply with permit effluent limits; PENALTY: $4,500; ENFORCEMENT COORDINATOR: Jorge Ibarra, (817) 588-5800; REGIONAL OFFICE: 2301 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(35) COMPANY: TXI Operations, LP; DOCKET NUMBER: 2007-0317-IWD-E; IDENTIFIER: RN100211283; LOCATION: Navarro County, Texas; TYPE OF FACILITY: lightweight aggregate production; RULE VIOLATED: 30 TAC §305.125(1), TPDES Permit Number 01691, Effluent Limitations and Monitoring Requirement Number 1, and the Code, §26.121(a), by failing to comply with the permitted effluent limits; PENALTY: $14,445; ENFORCEMENT COORDINATOR: Samuel Short, (512) 239-5363; REGIONAL OFFICE: 2301 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(36) COMPANY: Wilcrest Associate, Inc. dba Sunrise Super Stop 7; DOCKET NUMBER: 2007-0217-PST-E; IDENTIFIER: RN101801553; LOCATION: Houston, Harris County, Texas; TYPE OF FACILITY: convenience store with retail sales of gasoline; RULE VIOLATED: 30 TAC §334.72, by failing to report a suspected release; 30 TAC §334.74(1), by failing to investigate a suspected release; and 30 TAC §115.242(3) and THSC, §382.085(b), by failing to maintain the Stage II VRS in proper operating condition; PENALTY: $4,050; ENFORCEMENT COORDINATOR: Judy Kluge, (817) 588-5800; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

TRD-200702248
Mary R. Risner
Director, Litigation Division
Texas Commission on Environmental Quality
Filed: June 5, 2007

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Notice of District Petition

Notices issued June 1, 2007 through June 6, 2007.

TCEQ Internal Control No. 12072006-D03; 130 Cactus Investment, LP, Rebecca R. Hill, Frank Hill, et al. (Petitioners) filed a petition for creation of Travis County Municipal Utility District No. 17 (District) with the Texas Commission on Environmental Quality (TCEQ). The petition was filed pursuant to Article XVI, Section 59 of the Constitution of the State of Texas; Chapters 49 and 54 of the Texas Water Code; 30 TAC Chapter 293; and the procedural rules of the TCEQ. The petition states the following: (1) Rebecca R. Hill, Frank Hill, and 130 Cactus Investment, LP hold fee simple title to 162.17 acres to be included within the proposed District; (2) Jesse G. Bohls, Jr., Helen Bohls Weiss, Herbert W, Bohls, Joyce Bohls Teinert, Grace Bohls Scott, David Walenta, Cheryl Walenta, Amy Walenta, Belinda Walenta, Ruth Anderson, Nancy Baden, Ted Wayne Teinert, Carl Wayne Albers, Individually and as Independent Executor and Testamentary Trustee of the Trust Created under the Will in the Estate of Julia Maria Bohls, deceased, and 130 Cactus Investment, LP hold fee simple title to 237.56 acres to be included within the proposed District; (3) Kathleen Marie England and Jay Lawrence Johnson, who signed the petition, are the only lien holders on the 162.17 acres; (4) there are no lien holders on the 237.56 acres; (4) the proposed District will contain approximately 399.73 acres located in Travis County, Texas; and (5) all of the land to be included within the proposed District is within the extraterritorial jurisdiction of the City of Pflugerville, Texas. By Resolution No. 889-06-07-25-10C, effective July 25, 2006, the City of Pflugerville, Texas, gave its consent to the creation of the proposed District. According to the petition, the Petitioners have conducted a preliminary investigation to determine the cost of the project and from the information available at the time, the cost of the project is estimated to be approximately $29,810,000.

TCEQ Internal Control No. 01092007-D08; The Stoddard Group, Ltd. and TMI, Inc. (Petitioner) filed a petition for creation of Fort Bend County Municipal Utility District No. 171 (District) with the Texas Commission on Environmental Quality (TCEQ). The petition was filed

pursuant to Article XVI, Section 59 of the Constitution of the State of Texas; Chapters 49 and 54 of the Texas Water Code; 30 Texas Administrative Code Chapter 293; and the procedural rules of the TCEQ. The petition states the following: (1) the Petitioner is the owner of a majority in value of the land to be included in the proposed District; (2) there is one lien holder, Capital Farm Credit, FLCA, on the property to be included in the proposed District, and the Petitioner has provided the TCEQ with a certificate evidencing its consent to the creation of the proposed District; (3) the proposed District will contain approximately 552.4 acres of land located in Fort Bend County, Texas; and (4) the proposed District is entirely within the corporate boundaries of the City of Fulshear, Texas, and no portion of land within the proposed District is within the corporate limits or extraterritorial jurisdiction of any other city, town, or village of the State of Texas. By Resolution No. 06-135, effective December 19, 2006, the City of Fulshear, Texas, gave its consent to the creation of the proposed District. According to the petition, the Petitioner has conducted a preliminary investigation to determine the cost of the project and from the information available at the time, the cost of the project is estimated to be approximately $17,090,000.

TCEQ Internal Control No. 01092007-D06; The Stoddard Group Ltd., Katy Independent School District, and TMI Inc. (Petitioner) filed a petition for creation of Fort Bend County Municipal Utility District No. 173 (District) with the Texas Commission on Environmental Quality (TCEQ). The petition was filed pursuant to Article XVI, Section 59 of the Constitution of the State of Texas; Chapters 49 and 54 of the Texas Water Code; 30 Texas Administrative Code Chapter 293; and the procedural rules of the TCEQ. The petition states the following: (1) the Petitioner is the owner of a majority in value of the land to be included in the proposed District; (2) there is one lien holder, Capital Farm Credit, FLCA, on the property to be included in the proposed District, and the Petitioner has provided the TCEQ with a certificate evidencing the lien holder's consent to the creation of the proposed District; (3) the proposed District will contain approximately 567.3 acres of land located in Fort Bend County, Texas; and (4) the proposed District is entirely within the corporate boundaries of the City of Fulshear, Texas, and no portion of land within the proposed District is within the corporate limits or extraterritorial jurisdiction of any other city, town, or village of the State of Texas. By Resolution No. 06-135, effective December 19, 2006, the City of Fulshear, Texas, gave its consent to the creation of the proposed District. According to the petition, the Petitioners have conducted a preliminary investigation to determine the cost of the project and from the information available at the time, the cost of the project is estimated to be approximately $17,200,000.

TCEQ Internal Control No. 01092007-D07; The Stoddard Group, Ltd. and TMI, Inc. (Petitioner) filed a petition for creation of Fort Bend County Municipal Utility District No. 172 (District) with the Texas Commission on Environmental Quality (TCEQ). The petition was filed pursuant to Article XVI, Section 59 of the Constitution of the State of Texas; Chapters 49 and 54 of the Texas Water Code; 30 Texas Administrative Code Chapter 293; and the procedural rules of the TCEQ. The petition states the following: (1) the Petitioner is the owner of a majority in value of the land to be included in the proposed District; (2) there is one lien holder, Capital Farm Credit, FLCA, on the property to be included in the proposed District, and the Petitioner has provided the TCEQ with a certificate evidencing its consent to the creation of the proposed District; (3) the proposed District will contain approximately 910.0 acres of land located in Fort Bend County, Texas; and (4) the proposed District is entirely within the corporate boundaries of the City of Fulshear, Texas, and no portion of land within the proposed District is within the corporate limits or extraterritorial jurisdiction of any other city, town, or village of the State of Texas. By Resolution No. 06-135, effective December 19, 2006, the City of Fulshear, Texas, gave its consent to the creation of the proposed District. According to the petition, the Petitioner has conducted a preliminary investigation to determine the cost of the project and from the information available at the time, the cost of the project is estimated to be approximately $27,600,000.

TCEQ Internal Control No. 03152007-D06; Roman Forest Consolidated Municipal Utility District of Montgomery County has applied to the Texas Commission on Environmental Quality (TCEQ) for authority to adopt and impose an annual uniform operation and maintenance standby fee of $216 per equivalent single family connection for a period of three (3) years, on unimproved property within the District. The application was filed pursuant to Chapter 49 of the Texas Water Code, 30 Texas Administrative Code Chapter 293, and the procedural rules of the TCEQ. The TCEQ may approve the annual standby fee as requested, or it may approve a lower annual standby fee, but it shall not approve an annual standby fee greater than the amount requested. The standby fee is a personal obligation of the person owning the undeveloped property on January 1 of the year for which the fee is assessed. A person is not relieved of his pro-rated share of the standby fee obligation on transfer of title to the property. On January 1 of each year, a lien is attached to the undeveloped property to secure payment of any standby fee imposed and the interest or penalty, if any, on the fee. The lien has the same priority as a lien for taxes of the District. The TCEQ may grant a contested case hearing on this petition if a written hearing request is filed within 30 days after the newspaper publication of this notice.

INFORMATION SECTION

The TCEQ may grant a contested case hearing on the petition if a written hearing request is filed within 30 days after the newspaper publication of the notice. To request a contested case hearing, you must submit the following: (1) your name (or for a group or association, an official representative), mailing address, daytime phone number, and fax number, if any; (2) the name of the Petitioner and the TCEQ Internal Control Number; (3) the statement "(I/we) request a contested case hearing"; (4) a brief description of how you would be affected by the petition in a way not common to the general public; and (5) the location of your property relative to the proposed District's boundaries. You may also submit your proposed adjustments to the petition. Requests for a contested case hearing must be submitted in writing to the Office of the Chief Clerk at the address provided in the information section below. The Executive Director may approve the petition unless a written request for a contested case hearing is filed within 30 days after the newspaper publication of this notice. If a hearing request is filed, the Executive Director will not approve the petition and will forward the petition and hearing request to the TCEQ Commissioners for their consideration at a scheduled Commission meeting. If a contested case hearing is held, it will be a legal proceeding similar to a civil trial in state district court. Written hearing requests should be submitted to TCEQ, Office of the Chief Clerk, MC 105, P.O. Box 13087, Austin, TX 78711-3087. For information concerning the hearing process, please contact the Public Interest Counsel, MC 103, at the same address. For additional information, individual members of the general public may contact the Districts Review Team, at (512) 239-4691. Si desea información en Español, puede llamar al (512) 239-0200. General information regarding TCEQ can be found at our web site at www.tceq.state.tx.us.

TRD-200702271
LaDonna Castañuela
Chief Clerk
Texas Commission on Environmental Quality
Filed: June 6, 2007

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Notice of Meeting on July 19, 2007, in Mount Pleasant, Titus County, Texas Concerning the Former Dorchester Refining Company State Superfund Site

The purpose of the meeting is to obtain public input and information concerning the deletion of the site from its proposed status on the state Superfund registry.

The executive director (ED) of the Texas Commission on Environmental Quality (TCEQ or commission) is issuing a notice of intent to delete the Dorchester Refining Company state Superfund site (the site) from its proposed status on the state Superfund registry. The state Superfund registry is the list of state Superfund sites which may constitute an imminent and substantial endangerment to public health and safety or the environment due to a release or threatened release of hazardous substances into the environment. The commission is proposing this deletion because the site is expected to be addressed under the Voluntary Cleanup Program (VCP).

The site, including all land, structures, appurtenances, and other improvements, is approximately 138 acres and located in the 1700 block of West First Street in the city of Mount Pleasant, Titus County, Texas. The site also included any areas where hazardous substances had come to be located as a result, either directly or indirectly, of releases of hazardous substances from the site.

The facility formerly known as Dorchester Refining is located on the west border of the City of Mount Pleasant. The site is bordered by the St. Louis Southern Railroad on the south, suburban areas to the west and north, Conoco bulk terminal to the northeast and a residential area to the southeast. The description of the facility is based on the information available in 2003 when the site was evaluated with the Hazard Ranking System (HRS).

Dorchester Refining was an active refinery under several owners from 1936 to 1984, refining gasoline, diesel and asphalt products. Past refining operations at the site have resulted in impact to soils and sediments. Data collected by the TCEQ as part of the 2003 HRS indicate elevated levels of heavy metals (cadmium, chromium, lead and mercury) and semi-volatile constituents (pyrene, chrysene, benzo(b)- and benzo(k)-fluoranthene, benzo(a)pyrene, indeno(1,2,3-cd)pyrene, and benzo(g,h,i)perlyene) were detected in the soils. Heavy metals (cadmium, chromium, and lead) were also detected in the sediments of nearby Tankersley creek. The elevated levels of metals and semi-volatile organic constituents in soils and sediments are attributable to the former refining operations at the site.

In April 2007, TOTAL Petrochemicals USA, Inc. and SemCrude L.P applied for acceptance into the Voluntary Cleanup Program (VCP) to clean up the site. Notice will be filed with the deed for the site in the real property records in Titus County that residual contamination is present on site. The site was proposed to the state Superfund registry with a commercial /industrial land use designation according to the Texas Risk Reduction Program regulations (30 TAC §350.53).

The site is expected to be accepted into the TCEQ Voluntary Cleanup Program and therefore upon acceptance will be eligible for deletion from the state registry as provided by 30 TAC §335.344(c).

In accordance with 30 TAC §335.344(b), the commission will hold a public meeting to receive comment on this proposed deletion. This meeting will not be a contested case hearing within the meaning of Texas Government Code, Chapter 2001. The meeting will be held on July 19, 2007, at 7:00 p.m., at the Mount Pleasant Junior High School, located at 2801 Old Paris Road, Mount Pleasant, Texas 75455.

All persons desiring to make comments regarding the proposed deletion of the site may do so prior to or at the public meeting. All comments submitted prior to the public meeting must be received by 5:00 p.m on July 18, 2007 **and should be sent in writing** to Luda Voskov, Project Manager, TCEQ, Remediation Division, MC 143, P. O. Box 13087, Austin, Texas 78711-3087 (or by facsimile: (512) 239-2450). The public comment period for this action will end at the close of the public meeting on July 19, 2007.

A portion of the record for the site including documents pertinent to the ED's proposed deletion is available for review during regular business hours at the Mount Pleasant Public Library, located at 213 North Madison, Mount Pleasant, Texas 75445. The complete public file may be obtained during regular business hours at the commission's Records Management Center, Building E, First Floor, Records Customer Service, MC 199, 12100 Park 35 Circle, Austin, Texas 78753, (800) 633-9363 or (512) 239-2920. Photocopying of file information is subject to payment of a fee. Parking is available for persons with disabilities on the east side of Building D, convenient to access ramps that are between Buildings D and E.

Persons with disabilities who have special communication or other accommodation needs who are planning to attend the meeting should contact the agency at (800) 633-9363 or (512) 239-3844. Requests should be made as far in advance as possible.

For further information about the public meeting, please contact Crystal Taylor at (800) 633-9363.

TRD-200702234
Mary R. Risner
Director, Litigation Division
Texas Commission on Environmental Quality
Filed: June 4, 2007

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Notice of Opportunity to Comment on Default Orders of Administrative Enforcement Actions

The Texas Commission on Environmental Quality (TCEQ or commission) staff is providing an opportunity for written public comment on the listed Default Orders (DOs). The commission staff proposes a DO when the staff has sent an executive director's preliminary report and petition (EDPRP) to an entity outlining the alleged violations; the proposed penalty; and the proposed technical requirements necessary to bring the entity back into compliance; and the entity fails to request a hearing on the matter within 20 days of its receipt of the EDPRP or requests a hearing and fails to participate at the hearing. Similar to the procedure followed with respect to Agreed Orders entered into by the executive director of the commission, in accordance with Texas Water Code (TWC), §7.075 this notice of the proposed order and the opportunity to comment is published in the *Texas Register* no later than the 30th day before the date on which the public comment period closes, which in this case is **July 16, 2007**. The commission will consider any written comments received and the commission may withdraw or withhold approval of a DO if a comment discloses facts or considerations that indicate that consent to the proposed DO is inappropriate, improper, inadequate, or inconsistent with the requirements of the statutes and rules within the commission's jurisdiction, or the commission's orders and permits issued in accordance with the commission's regulatory authority. Additional notice of changes to a proposed DO is not required to be published if those changes are made in response to written comments.

A copy of each proposed DO is available for public inspection at both the commission's central office, located at 12100 Park 35 Circle, Building A, 3rd Floor, Austin, Texas 78753, (512) 239-3400 and at the applicable regional office listed as follows. Written comments about the DO should be sent to the attorney designated for the DO at the commission's central office at P.O. Box 13087, MC 175, Austin, Texas

78711-3087 and must be **received by 5:00 p.m. on July 16, 2007**. Comments may also be sent by facsimile machine to the attorney at (512) 239-3434. The commission's attorneys are available to discuss the DOs and/or the comment procedure at the listed phone numbers; however, §7.075 provides that comments on the DOs shall be submitted to the commission in **writing**.

(1) COMPANY: Birdsong Fuels & Services, L.L.C.; DOCKET NUMBER: 2005-1524-PST-E; TCEQ ID NUMBER: RN101813616; LOCATION: 860 Interstate Highway 10 South, Beaumont, Jefferson County, Texas; TYPE OF FACILITY: convenience store with retail sales of gasoline; RULES VIOLATED: 30 TAC §37.815(a) and (b), by failing to demonstrate acceptable financial assurance for taking corrective action and for compensating third parties for bodily injury and property damage caused by accidental releases arising from the operation of petroleum underground storage tanks (USTs); and 30 TAC §334.22(a) and Texas Water Code (TWC), §5.702, by failing to pay outstanding UST fees for TCEQ Account No. 0047647U for Fiscal Year 2005; PENALTY: $ 2,800; STAFF ATTORNEY: Lena Roberts, Litigation Division, MC 175, (512) 239-0019; REGIONAL OFFICE: Beaumont Regional Office, 3870 Eastex Freeway, Beaumont, Texas 77703-1892, (409) 898-3838.

(2) COMPANY: Brad Stricker; DOCKET NUMBER: 2005-0062-LII-E; TCEQ ID NUMBER: RN104211362; LOCATION: 330 Sollock Drive and 700 West Honda Avenue, Devine, Medina County, Texas; TYPE OF FACILITY: landscape irrigator system; RULES VIOLATED: 30 TAC §30.5(a) and (b), and §344.4(a), TWC, §37.003, and Texas Occupations Code, §1903.251, by failing to obtain a landscape irrigator's license prior to selling, designing, consulting, installing, maintaining, altering, repairing, or servicing two irrigation systems; PENALTY: $1,750; STAFF ATTORNEY: Lena Roberts, Litigation Division, MC 175, (512) 239-0019; REGIONAL OFFICE: San Antonio Regional Office, 14250 Judson Road, San Antonio, Texas 78233-4480, (210) 490-3096.

(3) COMPANY: Grayson Hilltop Estates Water Supply Corporation; DOCKET NUMBER: 2005-0606-PWS-E; TCEQ ID NUMBER: RN101231884; LOCATION: Fallon Drive, west of the Marshall Street intersection, Grayson County, Texas; TYPE OF FACILITY: public water supply; RULES VIOLATED: 30 TAC §290.46(e) and Texas Health and Safety Code (THSC), §341.033(a), by failing to employ a waterworks operator holding a valid Class D or higher operator's license; and 30 TAC §290.45(f)(3), by failing to secure a written contract, a signed document of specific terms, or a memorandum or letter of understanding between the purchaser and the wholesaler that establishes a maximum purchase rate sufficient to meet system requirements; PENALTY: $2,205; STAFF ATTORNEY: Xavier Guerra, Litigation Division, MC R-13, (210) 403-4016; REGIONAL OFFICE: Dallas-Fort Worth Regional Office, 2309 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(4) COMPANY: Feroz Ali Momin dba Snappy Mart; DOCKET NUMBER: 2005-0393-MLM-E; TCEQ ID NUMBER: RN102702339; LOCATION: 4303 East Highway 90, Crosby, Harris County, Texas; TYPE OF FACILITY: convenience store with retail sales of gasoline; RULES VIOLATED: TWC, §26.121(a), by failing to prevent an unauthorized discharge of hydrocarbons into or adjacent to waters in the State; and 30 TAC §§334.74(2)(A), 334.78 and 334.80(a)(4), by failing to conduct a release investigation and confirmation steps, the initial abatement steps, site assessment, and corrective action activities for the release of petroleum from the USTs; PENALTY: $17,780; STAFF ATTORNEY: Mary Hammer, Litigation Division, MC 175, (512) 239-2496; REGIONAL OFFICE: Houston Regional Office, 5425 Polk Street, Suite H, Houston, Texas 77023, (713) 767-3500.

(5) COMPANY: L & L AG Products, Inc. dba De Kalb City Cleaners; DOCKET NUMBER: 2006-1490-DCL-E; TCEQ ID NUMBER: RN105017735; LOCATION: 320 West Front Street, De Kalb, Bowie County, Texas; TYPE OF FACILITY: dry cleaning drop station; RULES VIOLATED: 30 TAC §337.10(a), and THSC, §374.102, by failing to complete and submit the required registration form to the TCEQ for a dry cleaning and/or drop station facility; PENALTY: $1,185; STAFF ATTORNEY: Dinniah Chahin, Litigation Division, MC 175, (512) 239-0617; REGIONAL OFFICE: Tyler Regional Office, 2916 Teague Drive, Tyler, Texas 75701-3756, (903) 535-5100.

(6) COMPANY: Willie Scales dba Starchy Down Cleaners Kirkwood and dba Starchy Down Cleaners; DOCKET NUMBER: 2006-1240-DCL-E; TCEQ ID NUMBER: RN104964648; LOCATION: 9803 South Kirkwood Road (Facility 1), 10949 South Sam Houston Parkway West (Facility 2), Houston, Harris County, Texas; TYPE OF FACILITY: dry cleaning and/or drop station facilities; RULES VIOLATED: 30 TAC §337.10(a) and THSC, §374.102, by failing to complete and submit the required registration from to the TCEQ for Facility 1 for Fiscal Year 2006; 30 TAC §337.10(a) and THSC, §374.102, by failing to complete and submit the required registration form to the TCEQ for Facility 2 for Fiscal Year 2006; and 30 TAC §337.14(c) and TWC, §5.702, by failing to pay Dry Cleaner Registration Fees for TCEQ Financial Administration Account No. 24002797 for Fiscal Year 2004 and 2005 and associated late fees; PENALTY: $2,370; STAFF ATTORNEY: Ben Thompson, Litigation Division, MC 175, (512) 239-1297; REGIONAL OFFICE: Houston Regional Office, 5425 Polk Street, Suite H, Houston, Texas 77023, (713) 767-3500.

TRD-200702254
Mary R. Risner
Director, Litigation Division
Texas Commission on Environmental Quality
Filed: June 5, 2007

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Notice of Opportunity to Comment on Settlement Agreements of Administrative Enforcement Actions

The Texas Commission on Environmental Quality (TCEQ or commission) staff is providing an opportunity for written public comment on the listed Agreed Orders (AOs) in accordance with Texas Water Code (TWC), §7.075. Section 7.075 requires that before the commission may approve the AOs, the commission shall allow the public an opportunity to submit written comments on the proposed AOs. Section 7.075 requires that notice of the opportunity to comment must be published in the *Texas Register* no later than the 30th day before the date on which the public comment period closes, which in this case is **July 16, 2007**. Section 7.075 also requires that the commission promptly consider any written comments received and that the commission may withdraw or withhold approval of an AO if a comment discloses facts or considerations that indicate that consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the statutes and rules within the commission's jurisdiction or the commission's orders and permits issued in accordance with the commission's regulatory authority. Additional notice of changes to a proposed AO is not required to be published if those changes are made in response to written comments.

A copy of each proposed AO is available for public inspection at both the commission's central office, located at 12100 Park 35 Circle, Building A, 3rd Floor, Austin, Texas 78753, (512) 239-3400 and at the applicable regional office listed as follows. Written comments about an AO should be sent to the attorney designated for the AO at the commission's central office at P.O. Box 13087, MC 175, Austin, Texas

78711-3087 and must be **received by 5:00 p.m. on July 16, 2007**. Comments may also be sent by facsimile machine to the attorney at (512) 239-3434. The designated attorney is available to discuss the AO and/or the comment procedure at the listed phone number; however, §7.075 provides that comments on an AO shall be submitted to the commission in **writing**.

(1) COMPANY: Cardinal Towing Company, Inc. dba Cardinal Towing & Auto Repair; DOCKET NUMBER: 2006-1843-PST-E; TCEQ ID NUMBER: RN101536951; LOCATION: 113 West Euless Boulevard, Euless, Tarrant County, Texas; TYPE OF FACILITY: fleet refueling station; RULES VIOLATED: 30 TAC §334.50(b)(1)(A) and Texas Water Code (TWC), §26.3475(c)(1), by failing to ensure that all underground storage tanks (USTs) are monitored for releases at a frequency of at least once every month (not to exceed 35 days between each monitoring); PENALTY: $2,300; STAFF ATTORNEY: Dinniah Chahin, Litigation Division, MC 175, (512) 239-0617; REGIONAL OFFICE: Dallas-Fort Worth Regional Office, 2309 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(2) COMPANY: Cruz Mendez dba New Way; DOCKET NUMBER: 2004-0716-PST-E; TCEQ ID NUMBER: RN102345097; LOCATION: 4306 West Marshall Avenue, Longview, Gregg County, Texas; TYPE OF FACILITY: convenience store with retail sales of gasoline; RULES VIOLATED: TWC, §26.3475(a) and §26.3475(c)(1), and 30 TAC §334.50(a)(1)(A), by failing to have a release detection method capable of detecting a release from any portion of the UST system which contains regulated substances including tanks, piping and other ancillary equipment; TWC, §26.3475(c)(2) and 30 TAC §334.51(b)(2)(C), by failing to have overfill prevention equipment for five USTs; 30 TAC §334.49(c)(2)(C), by failing to check the impressed current corrosion protection system once every 60 days; and 30 TAC §334.48(c), by failing to conduct effective manual or automatic inventory control procedures for all USTs at a retail service station; PENALTY: $16,500; STAFF ATTORNEY: Robert Mosley, Litigation Division, MC 175, (512) 239-0627; REGIONAL OFFICE: Tyler Regional Office, 2916 Teague Drive, Tyler, Texas 75701-3756, (903) 535-5100.

(3) COMPANY: Imran Khan dba Stop n Drive; DOCKET NUMBER: 2006-2179-PST-E; TCEQ ID NUMBER: RN102855053; LOCATION: 1708 Highway 146 North, La Porte, Harris County, Texas; TYPE OF FACILITY: convenience store with retail sales of gasoline; RULES VIOLATED: 30 TAC §37.815(a) and (b), by failing to demonstrate acceptable financial assurance for taking corrective action and for compensating third parties for bodily injury and property damage caused by accidental releases from the operation of petroleum USTs; PENALTY: $1,580; STAFF ATTORNEY: Tracy Chandler, Litigation Division, MC 175, (512) 239-0629; REGIONAL OFFICE: Houston Regional Office, 5425 Polk Street, Suite H, Houston, Texas 77023, (713) 767-3500.

(4) COMPANY: Inara Convenience, Inc. dba Rosedale Texaco; DOCKET NUMBER: 2005-0372-PST-E; TCEQ ID NUMBER: RN101534790; LOCATION: 6101 East Rosedale Street, Fort Worth, Tarrant County, Texas; TYPE OF FACILITY: convenience store with retail sales of gasoline; RULES VIOLATED: 30 TAC §37.815(a) and (b), by failing to demonstrate acceptable financial assurance for taking corrective action and for compensating third parties for bodily injury and property damage caused by accidental releases arising from the operation of two petroleum USTs; PENALTY: $2,620; STAFF ATTORNEY: Kathleen Decker, Litigation Division, MC 175, (512) 239-6500; REGIONAL OFFICE: Dallas-Fort Worth Regional Office, 2309 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(5) COMPANY: Inara Convenience, Inc, dba Rosedale Texaco; DOCKET NUMBER: 2006-0123-PST-E; TCEQ ID NUMBER: RN101534790; LOCATION: 6101 East Rosedale Street, Fort Worth, Tarrant County, Texas; TYPE OF FACILITY: convenience store with retail sales of gasoline; RULES VIOLATED: 30 TAC §334.50(b), (b)(1)(A), (b)(2), and (b)(2)(A)(i)(III); and TWC, §26.3475(a) and (c)(1); and Agreed Order Docket No. 2003-1588-PST-E, Ordering Provision No. 2.b., by failing to monitor its USTs for releases at a frequency of at least once every month (not to exceed 35 days between each monitoring) by using one or more of the release detection methods and, by failing to monitor pressurized piping associated with the UST system in a manner designed to detect releases from any portion of the piping system; 30 TAC §334.48(c) and Agreed Order Docket No. 2003-1588-PST-E, Ordering Provision No. 2.a., by failing to conduct effective manual or automatic inventory control procedures for all USTs involved in the retail sale of petroleum substances used as a motor fuel; and 30 TAC §334.8(c)(5)(C), by failing to ensure that a legible tag, label, or marking with the tank number was permanently applied upon or affixed to either the top of the fill tube or to a non-removable point in the immediate area of the fill tube according to the UST registration and self-certification form; PENALTY: $40,610; STAFF ATTORNEY: Kathleen Decker, Litigation Division, MC 175, (512) 239-6500; REGIONAL OFFICE: Dallas-Fort Worth Regional Office, 2309 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(6) COMPANY: North Bengal, Inc. dba Dry Clean Super Center; DOCKET NUMBER: 2006-0870-DCL-E; TCEQ ID NUMBER: RN104091012; LOCATION: 1301 North Main Street, Euless, Tarrant County, Texas; TYPE OF FACILITY: dry cleaner facility; RULES VIOLATED: 30 TAC §337.11(e) and Texas Health and Safety Code (THSC), §374.102, by failing to renew the facility's registration by completing and submitting the required registration form to the TCEQ for the facility; PENALTY: $889; STAFF ATTORNEY: Mary Hammer, Litigation Division, MC 175, (512) 239-2496; REGIONAL OFFICE: Dallas-Fort Worth Regional Office, 2309 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(7) COMPANY: Robert Durham dba A & A Auto Parts and Rebuilders; DOCKET NUMBER: 2006-0506-WQ-E; TCEQ ID NUMBER: RN104726831; LOCATION: 7752 Mansfield Highway, Kennedale, Tarrant County, Texas; TYPE OF FACILITY: automobile salvage yard; RULES VIOLATED: 30 TAC §281.25(a)(4) and 40 Code of Federal Regulation (CFR), §122.26(c) by failing to obtain authorization to discharge storm water associated with industrial activity to water in the state through an individual permit or a Texas Pollutant Discharge Elimination System (TPDES) Multi-Sector General Permit; and 30 TAC §21.4(f), and TWC, §5.702 by failing to pay general storm water permit fees for TCEQ Account No. 20001206 and associated late fees for Fiscal Years 2003-2005; PENALTY: $2,040; STAFF ATTORNEY: Justin Lannen, Litigation Division, MC R-4, (817) 588-5927; REGIONAL OFFICE: Dallas-Fort Worth Regional Office, 2309 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(8) COMPANY: Song Jung dba New Core Cleaners; DOCKET NUMBER: 2006-0793-DCL-E; TCEQ ID NUMBER: RN104962287; LOCATION: 1512 East Exchange Parkway, Suite 300, Allen, Collin County, Texas; TYPE OF FACILITY: dry cleaning drop station; RULES VIOLATED: 30 TAC §337.10(a) and THSC, §374.102, by failing to complete and submit the required registration form to the TCEQ for a dry cleaning and/or drop station facility; PENALTY: $1,067; STAFF ATTORNEY: Mary Hammer, Litigation Division, MC 175, (512) 239-2496; REGIONAL OFFICE: Dallas-Fort Worth Regional Office, 2309 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(9) COMPANY: T.T.X., Inc.; DOCKET NUMBER: 2005-2080-PST-E; TCEQ ID NUMBER: RN101648079; LOCATION: 2300

Time Street, Irving, Dallas County, Texas; TYPE OF FACILITY: trucking terminal; RULES VIOLATED: 30 TAC §37.815(a) and (b), by failing to demonstrate acceptable financial assurance for taking corrective action for compensating third parties for bodily injury and property damage caused by accidental releases arising from the operation of petroleum USTs; PENALTY: $3,150; STAFF ATTORNEY: Mary Hammer, Litigation Division, MC 175, (512) 239-2496; REGIONAL OFFICE: Dallas-Fort Worth Regional Office, 2309 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

TRD-200702253
Mary R. Risner
Director, Litigation Division
Texas Commission on Environmental Quality
Filed: June 5, 2007

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Notice of Water Quality Applications

The following notices were issued during the period of May 24, 2007 through June 1, 2007.

The following require the applicants to publish notice in a newspaper. Public comments, requests for public meetings, or requests for a contested case hearing may be submitted to TCEQ, Office of the Chief Clerk, Mail Code 105, P.O. Box 13087, Austin Texas 78711-3087, WITHIN 30 DAYS OF THE DATE OF NEWSPAPER PUBLICATION OF THE NOTICE.

ALGONQUIN WATER RESOURCES OF TEXAS, LLC has applied for a renewal of TPDES Permit No. WQ0013417001 which authorizes the discharge of treated domestic wastewater at a daily average flow not to exceed 200,000 gallons per day. The facility is located approximately 0.2 miles north of the intersection of League Line Road and Piney Shores Drive in Conroe, in Montgomery County, Texas.

ARANSAS COUNTY MUNICIPAL UTILITY DISTRICT NO. 1 has applied for a major amendment to TCEQ Permit No. 11624-001 to authorize a discharge of treated domestic wastewater to a receiving body of water and an increase in the discharge of treated domestic wastewater from a daily average flow not to exceed 88,000 gallons per day via irrigation to a daily average flow not to exceed 263,000 gallons per day via discharge to a receiving body of water. The current permit authorizes the disposal of treated domestic wastewater via irrigation of 44.4 acres of public access land. The facility is located approximately 1,100 feet south of 8th Street and approximately 500 feet west of Park Road 13 (Palmetto Drive) in the Lamar Peninsula in Aransas County, Texas. The TCEQ Executive Director has reviewed this action for consistency with the Texas Coastal Management Program goals and policies in accordance with the regulations of the Coastal Coordination Council and has determined that the action is consistent with the applicable CMP goals and policies.

CASTLEWOOD MUNICIPAL UTILITY DISTRICT has applied for a renewal of TPDES Permit No. WQ0011883001, which authorizes the discharge of treated domestic wastewater at an annual average flow not to exceed 2,000,000 gallons per day. The facility is located 500 feet north of Interstate Highway 10, 2,600 feet east of where Interstate Highway 10 crosses Mason Creek, and 6,300 feet west of Fry Road in Harris County, Texas.

LOWER COLORADO RIVER AUTHORITY has applied for a renewal of TPDES Permit No. 14404-001, which authorizes the discharge of treated domestic wastewater at a daily average flow not to exceed 25,000 gallons per day. The facility is located approximately 2,700 feet east of Farm-to-Market Road 2031 (Beach Road) and approximately 1,200 feet north of the Gulf of Mexico in Matagorda County, Texas.

MA SEDONA LAKES, LP has applied for a new permit, proposed Texas Pollutant Discharge Elimination System (TPDES) Permit No. WQ0014756001, to authorize the discharge of treated domestic wastewater at a daily average flow not to exceed 600,000 gallons per day. The facility will be located 1.1 miles east-northeast of the intersection of State Highway 288 and County Road 58 in Brazoria County, Texas.

CITY OF OAKWOOD has applied for a renewal of TPDES Permit No. 10586-002, which authorizes the discharge of treated domestic wastewater at a daily average flow not to exceed 176,000 gallons per day. The facility is located approximately 1,600 feet south-southeast of the intersection of Farm-to-Market Road 831 and Farm-to-Market Road 542, southeast of the City of Oakwood in Leon County, Texas.

CITY OF SCHULENBURG has applied for a renewal of TPDES Permit No. 10115-002, which authorizes the discharge of treated domestic wastewater at a daily average flow not to exceed 250,000 gallons per day. The facility is located approximately 500 feet west of the intersection of Babylon Lane and Williams Avenue in the City of Schulenburg in Fayette County, Texas.

TEXAS MILITARY FACILITIES COMMISSION has applied for a renewal of TPDES Permit No. 13249-001, which authorizes the discharge of treated domestic wastewater at a daily average flow not to exceed 7,000 gallons per day. The facility is located approximately 1/2 mile southeast of the intersection of U.S. Highway 271 and Farm-to-Market Road 2648 in Lamar County, Texas.

CITY OF WHITEFACE has applied to the TCEQ for a major amendment to Permit No. WQ0010314001, to authorize an increase in the daily average flow from 35,000 gallons per day to 62,000 gallons per day. The current permit authorizes the disposal of treated domestic wastewater at a daily average flow not to exceed 35,000 gallons per day via evaporation. This permit will not authorize a discharge of pollutants into waters in the State. The wastewater treatment facility and disposal site are located approximately 2,500 feet northeast of the intersection of State Highway 114 and Farm-to-Market Road 1780, north of the City of Whiteface in Cochran County, Texas.

INFORMATION SECTION

To view the complete issued notices, view the notices on our web site at www.tceq.state.tx.us/comm_exec/cc/pub_notice.html or call the Office of the Chief Clerk at (512) 239-3300 to obtain a copy of the complete notice. When searching the web site, type in the issued date range shown at the top of this document to obtain search results.

If you need more information about these permit applications or the permitting process, please call the TCEQ Office of Public Assistance, Toll Free, at 1-800-687-4040. General information about the TCEQ can be found at our web site at www.tceq.state.tx.us. Si desea información en Español, puede llamar al 1-800-687-4040.

TRD-200702269
LaDonna Castañuela
Chief Clerk
Texas Commission on Environmental Quality
Filed: June 6, 2007

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Notice of Water Rights Applications

Notices issued May 16 through June 6, 2007.

APPLICATION NO. 12159; James E. Mauldin, Trustee, (Applicant), 923 West Loop 281, Longview, Texas 75604, has applied for a Water

Use Permit to construct and maintain two (2) dams and reservoirs on an unnamed tributary of Long Creek, Sabine River Basin, for in-place recreational purposes in Gregg County. The application and partial fees were received on February 12, 2007; and additional information was received on March 19, and April 11, 2007. The application was declared administratively complete and accepted for filing with the Office of the Chief Clerk on April 11, 2007. Written public comments and requests for a public meeting should be submitted to the Office of Chief Clerk at the address provided in the information section below within 30 days of the date of newspaper publication of the notice.

APPLICATION NO. 4404B; WSG Thorntree IV, L.P., A Delaware Limited Partnership, Applicant, 5080 Spectrum Drive, Suite No. 1000 East, Addison, Texas 75001, has applied for an amendment to Water Use Permit No. 4066, (Application No. 4404) to extend the expiration date for an additional ten years for diversion and use of State water from Ten Mile Creek, Trinity River Basin for agricultural (irrigation) purposes in Dallas County, Texas. The application was received on December 15, 2006. Additional information and fees for the application was received on March 9, 2007. The application was accepted for filing and declared administratively complete on March 23, 2007. Written public comments and requests for a public meeting should be submitted to the Office of Chief Clerk at the address provided in the information section below within 30 days of the date of newspaper publication of the notice.

INFORMATION SECTION

To view the complete issued notice, view the notice on our web site at www.tceq.state.tx.us/comm_exec/cc/pub_notice.html or call the Office of the Chief Clerk at (512) 239-3300 to obtain a copy of the complete notice. When searching the web site, type in the issued date range shown at the top of this document to obtain search results.

A public meeting is intended for the taking of public comment and is not a contested case hearing.

The Executive Director can consider approval of an application unless a written request for a contested case hearing is filed. To request a contested case hearing, you must submit the following: (1) your name (or for a group or association, an official representative); mailing address; daytime phone number; and fax number, if any; (2) applicant's name and permit number; (3) the statement "(I/we) request a contested case hearing"; and (4) a brief and specific description of how you would be affected by the application in a way not common to the general public. You may also submit any proposed conditions to the requested application which would satisfy your concerns. Requests for a contested case hearing must be submitted in writing to the TCEQ Office of the Chief Clerk at the address provided in the information section below.

If a hearing request is filed, the Executive Director will not issue the requested permit and may forward the application and hearing request to the TCEQ Commissioners for their consideration at a scheduled Commission meeting.

Written hearing requests, public comments, or requests for a public meeting should be submitted to TCEQ Office of the Chief Clerk, MC 105, P.O. Box 13087, Austin, TX 78711-3087. For information concerning the hearing process, please contact the Public Interest Counsel, MC 103, at the same address. For additional information, individual members of the general public may contact the Office of Public Assistance at 1-800-687-4040. General information regarding the TCEQ can be found at our web site at www.tceq.state.tx.us. Si desea información en Español, puede llamar al 1-800-687-4040.

TRD-200702270

LaDonna Castañuela

Chief Clerk

Texas Commission of Environmental Quality

Filed: June 6, 2007

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Proposal for Decision

The State Office of Administrative Hearings issued a Proposal for Decision and Order to the Texas Commission on Environmental Quality on May 31, 2007, in the matter of the Executive Director of the Texas Commission on Environmental Quality, Petitioner v. Chester L. Slay, Jr.; SOAH Docket No. 582-04-0251; TCEQ Docket No. 2000-0396-IHW-E. The commission will consider the Administrative Law Judge's Proposal for Decision and Order regarding the enforcement action against Chester L. Slay, Jr. on a date and time to be determined by the Office of the Chief Clerk in Room 201S of Building E, 12100 N. Interstate 35, Austin, Texas. This posting is Notice of Opportunity to Comment on the Proposal for Decision and Order. The comment period will end 30 days from date of this publication. Written public comments should be submitted to TCEQ, Office of the Chief Clerk, MC-105, P.O. Box 13087, Austin, Texas 78711-3087. If you have any questions or need assistance, please contact Paul Munguía, Office of the Chief Clerk, (512) 239-3300.

TRD-200702272

LaDonna Castañuela

Chief Clerk

Texas Commission on Environmental Quality

Filed: June 6, 2007

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Proposal for Decision

The State Office of Administrative Hearings issued a Proposal for Decision and Order to the Texas Commission on Environmental Quality on May 23, 2007, in the matter of the Executive Director of the Texas Commission on Environmental Quality, Petitioner v. Dirgin Water Supply Corporation; SOAH Docket No. 582-07-0267; TCEQ Docket No. 2005-1818-PWS-E. The commission will consider the Administrative Law Judge's Proposal for Decision and Order regarding the enforcement action against Dirgin Water Supply Corporation on a date and time to be determined by the Office of the Chief Clerk in Room 201S of Building E, 12100 N. Interstate 35, Austin, Texas. This posting is Notice of Opportunity to Comment on the Proposal for Decision and Order. The comment period will end 30 days from date of this publication. Written public comments should be submitted to TCEQ, Office of the Chief Clerk, MC-105, P.O. Box 13087, Austin, Texas 78711-3087. If you have any questions or need assistance, please contact Paul Munguía, Office of the Chief Clerk, (512) 239-3300.

TRD-200702273

LaDonna Castañuela

Chief Clerk

Texas Commission on Environmental Quality

Filed: June 6, 2007

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Proposal for Decision

The State Office of Administrative Hearings issued a Proposal for Decision and Order to the Texas Commission on Environmental Quality on May 29, 2007, in the matter of the Executive Director of the Texas Commission on Environmental Quality, Petitioner v. Nick Nikah; SOAH Docket No. 582-07-1759; TCEQ Docket No.

2006-0774-LII-E. The commission will consider the Administrative Law Judge's Proposal for Decision and Order regarding the enforcement action against Nick Nikah on a date and time to be determined by the Office of the Chief Clerk in Room 201S of Building E, 12100 N. Interstate 35, Austin, Texas. This posting is Notice of Opportunity to Comment on the Proposal for Decision and Order. The comment period will end 30 days from date of this publication. Written public comments should be submitted to TCEQ, Office of the Chief Clerk, MC-105, P.O. Box 13087, Austin, Texas 78711-3087. If you have any questions or need assistance, please contact Paul Munguía, Office of the Chief Clerk, (512) 239-3300.

TRD-200702274
LaDonna Castañuela
Chief Clerk
Texas Commission on Environmental Quality
Filed: June 6, 2007

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Proposal for Decision

The State Office of Administrative Hearings issued a Proposal for Decision and Order to the Texas Commission on Environmental Quality on June 4, 2007, in the matter of the Executive Director of the Texas Commission on Environmental Quality, Petitioner v. Doris Bullock dba Bullock's Mobile Home Park; SOAH Docket No. 582-06-1637; TCEQ Docket No. 2005-1042-OSS-E. The commission will consider the Administrative Law Judge's Proposal for Decision and Order regarding the enforcement action against Doris Bullock dba Bullock's Mobile Home Park on a date and time to be determined by the Office of the Chief Clerk in Room 201S of Building E, 12100 N. Interstate 35, Austin, Texas. This posting is Notice of Opportunity to Comment on the Proposal for Decision and Order. The comment period will end 30 days from date of this publication. Written public comments should be submitted to TCEQ, Office of the Chief Clerk, MC-105, P.O. Box 13087, Austin, Texas 78711-3087. If you have any questions or need assistance, please contact Paul Munguía, Office of the Chief Clerk, (512) 239-3300.

TRD-200702275
LaDonna Castañuela
Chief Clerk
Texas Commission on Environmental Quality
Filed: June 6, 2007

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Request for Nominations

The Texas Commission on Environmental Quality (TCEQ) is requesting nominations for six individuals to serve on the Municipal Solid Waste Management and Resource Recovery Advisory Council (Council) for the following positions. The appointments will be made by the TCEQ Commissioners.

1. An elected official from a city with a population between 25,000 and 100,000 (expires August 31, 2013);

2. A representative of the financial community (expires August 31, 2013);

3. A representative from a solid waste management organization composed primarily of commercial operators (expires August 31, 2013);

4. Two representatives from the "general public" (one position expires August 31, 2011; the 2nd position expires August 31, 2013). To qualify for this position, the individual must not qualify for any of the other sixteen Council categories; and

5. A person who is experienced in the management and operation of a composting or recycling facility or an educator with knowledge of the design and management of solid waste facilities (expires August 31, 2013).

The Council was created by the 69th Legislature in 1983. Members represent various interests; i.e., city and county solid waste agencies, public solid waste district or authority, commercial solid waste landfill operators, planning regions, an environmentalist, city and county officials, financial advisor, registered waste tire processor, professional engineer, solid waste professional, composting/recycling manager and two general public representatives.

Upon request from the TCEQ Commissioners, the Council reviews and evaluates the effect of state policies and programs on municipal solid waste management; makes recommendations on matters relating to municipal solid waste management; recommends legislation to encourage the efficient management of municipal solid waste; recommends policies for the use, allocation, or distribution of the planning fund; and recommends special studies and projects to further the effectiveness of municipal solid waste management and recovery for the state of Texas.

The Council members are required by law to hold at least one meeting every three months. The meetings usually last one day and are held in Austin, Texas. Limited travel funds may be available. Additional information about the Council is available at: http://www.tceq.state.tx.us/permitting/waste_permits/adv-groups/msw_advcouncil.html.

To nominate an individual: 1) ensure the individual is qualified for the position which he/she is being considered; 2) submit a biographical summary which includes work experience; and 3) provide the nominee a copy of this request. The nominee needs to submit a letter indicating his/her agreement to serve, if appointed.

All applications and nominations should clearly indicate for which position they wish to be considered and that they meet the requirements for the specific position. If applying for "a representative for the general public" position, applicants must not have any conflicts of interest and will be asked for additional information.

The deadline for written nominations and letters from nominees must be received by the TCEQ by 5:00 p.m., on July 13, 2007. The appointments will be considered at a future Commissioner's Work Session in Austin, Texas.

Please submit all correspondence to: Steve Hutchinson, Waste Permits Division, TCEQ, P.O. Box 13087, MC 126, Austin, Texas 78711-3087 or fax (512) 239-2007. Questions regarding the Council can be directed to Mr. Hutchinson at (512) 239-6716 or e-mail to shutchin@tceq.state.tx.us.

TRD-200702226
Robert Martinez
Director, Environmental Law Division
Texas Commission on Environmental Quality
Filed: June 4, 2007

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General Land Office

Notice of Contract for Major Consulting Services

The General Land Office (the "GLO") is a participant in a project for the analysis and comparison of related data to National Ocean Service ("NOS") National Standards And Proceedings (hereinafter the "Standards") of a comprehensive tide monitoring and gauging system known as the Texas Coastal Ocean Observation Network ("TCOON"). Par-

ticipants include NOS, the Conrad Blucher Institute of Texas A&M University at Corpus Christi, and the U.S. Army Corps of Engineers ("COE"). TCOON is funded and administered through the cooperative effort of NOS, GLO, and COE.

Pursuant to §§2254.021 through 2254.040 of the Texas Government Code, the GLO is requesting offers for consulting services to assist with the review and analysis of tide and water level data received from the operation of TCOON during the two-year period from September 1, 2007 through August 31, 2009.

The requested consultant services will require an understanding of ocean tide gauging systems and time series analysis as performed by the NOS. The consultant selected to provide these services will be responsible for: (i) Coordination with NOS to ensure compliance with the Standards; (ii) Coordination of operational reporting with other project participants; and (iii) Inspecting and verifying station levels, stability, and locations.

The GLO has previously contracted for these consulting services, but intends to contract with a new consultant. The GLO reserves the right to evaluate the qualifications and experience of all Respondents, to reject any and/or all responses, and to negotiate specific terms of an agreement that is in the best interest of the state. The closing date for receipt of offers of these consulting services is 5:00 p.m. CDT, July 16, 2007. Further information may be obtained by contacting LaNell Aston, General Land Office, 1700 N. Congress Avenue, Austin, TX 78701-1495, phone (512) 936-1921.

TRD-200702268
Larry L. Laine
Chief Clerk, Deputy Land Commissioner
General Land Office
Filed: June 6, 2007

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Department of State Health Services

Notice of Agreed Orders

Notice is hereby given that the Department of State Health Services issued Agreed Orders to the following registrants:

Okomed Downtown Imaging, Inc. (Registration #R30151) of Houston. A total penalty of $500 shall be paid by registrant for violations of 25 Texas Administrative Code (TAC) Chapter 289. The registrant shall also comply with additional settlement agreement requirements.

Bower Central Texas Imaging (Registration #R28686) of New Braunfels. A total penalty of $500 shall be paid by registrant for violations of 25 TAC Chapter 289. The registrant shall also comply with additional settlement agreement requirements.

Team Industrial Services, Inc. (License #L00087) of Houston. A total penalty of $2,000 shall be paid by registrant for violations of 25 TAC Chapter 289. The registrant shall also comply with additional settlement agreement requirements.

Charles D. O'Dell, DDS (Registration #R05523) of Houston. A total penalty of $1,000 shall be paid by registrant for violations of 25 TAC Chapter 289. The registrant shall also comply with additional settlement agreement requirements.

A copy of all relevant material is available, by appointment, for public inspection at the Department of State Health Services, Exchange Building, 8407 Wall Street, Austin, Texas, telephone (512) 834-6688, press "1" then press "0," Monday - Friday, 8:00 a.m. to 5:00 p.m. (except holidays).

TRD-200702201
Lisa Hernandez
Deputy General Counsel
Department of State Health Services
Filed: June 4, 2007

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Notice of Emergency Cease and Desist Order on Martin E. McGonagle, M.D., P.A.

Notice is hereby given that the Department of State Health Services ordered Martin E. McGonagle, M.D., P.A. (registrant R16136-001) of Stephenville to cease and desist using the Fischer x-ray unit until the entrance exposure radiation levels are within regulatory limits.

A copy of all relevant material is available, by appointment, for public inspection at the Department of State Health Services, Exchange Building, 8407 Wall Street, Austin, Texas, telephone (512) 834-6688, Monday - Friday, 8:00 a.m. to 5:00 p.m. (except holidays).

TRD-200702251
Lisa Hernandez
Deputy General Counsel
Department of State Health Services
Filed: June 5, 2007

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Notice of Emergency Impoundment Order on Aztec Manufacturing Partnership, Ltd.

Notice is hereby given that the Department of State Health Services (department) ordered all radioactive material located at Aztec Manufacturing Partnership, Ltd. (unlicensed), Crowley, be impounded and not transferred without written authorization by the department.

A copy of all relevant material is available, by appointment, for public inspection at the Department of State Health Services, Exchange Building, 8407 Wall Street, Austin, Texas, telephone (512) 834-6688, Monday - Friday, 8:00 a.m. to 5:00 p.m. (except holidays).

TRD-200702252
Lisa Hernandez
Deputy General Counsel
Department of State Health Services
Filed: June 5, 2007

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Texas Department of Housing and Community Affairs

Notice of Public Hearings--Community Services Block Grant

As part of the public information consultation and public hearings requirements for the Community Services Block Grant, a federal block grant, the Texas Department of Housing and Community Affairs (TDHCA) is conducting four public hearings. The primary purpose of the hearings is to solicit comments on the proposed use and distribution of federal fiscal year (FFY) 2008-2009 funds provided under the Community Services Block Grant (CSBG) and to receive public comment on the Draft Community Services Block Grant State Plan and Application for 2008-2009.

The schedule for the four public hearings is as follows:

Monday, July 9, 2007

6:00 p.m.

Texas Department of Housing and Community Affairs

221 East 11th Street, room #116

Austin, Texas 78701

Tuesday, July 10, 2007

2:00 p.m.

Dallas Urban League

4315 South Lancaster

Dallas, Texas 75216

Wednesday, July 11, 2007

6:00 p.m.

City of Lubbock, City Hall Municipal Building

1625 13th Street, room 101

Lubbock, Texas 79457

Thursday, July 12, 2007

2:00 p.m.

Gulf Coast Community Services Association

5000 Gulf Freeway, Building 1

Houston, Texas 77023

Individuals who require auxiliary aids or services should contact Gina Esteves, ADA Responsible Employee, at least two days before the scheduled hearing at (512) 475-3943 so that appropriate arrangements can be made.

A representative from TDHCA will be present to explain the planning process and receive comments from interested citizens and affected groups regarding the proposed plan. The Draft Community Services Block Grant State Plan and Application for 2008-2009 may be obtained on or about July 2, 2007 by contacting the Texas Department of Housing and Community Affairs, Community Affairs Division, Community Services Section, P. O. Box 13941, Austin, Texas 78711-3941 or calling (512) 475-3905. For questions, contact the Community Services Section at (512) 475-3905. Comments on the plan may be in the form of written comments or oral testimony at the hearings or submitted by mail to TDHCA at the address previously provided or by e-mail to rita.garza@tdhca.state.tx.us. Comments must be received no later than July 12, 2007.

TRD-200702277
Michael Gerber
Executive Director
Texas Department of Housing and Community Affairs
Filed: June 6, 2007

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Texas State Library and Archives Commission

Request for Proposal (RFP) for Consulting Services

The Texas State Library and Archives Commission (TSLAC) intends to seek professional consulting services to evaluate its interlibrary loan program. The result of this study will provide valuable information to TSLAC in order to examine options for meeting interlibrary loan needs in terms of costs and benefits and provide a blueprint for building interlibrary loan services at the state level into the future. The study will also help TSLAC to determine the needs of the Texas interlibrary loan community as they strive to meet patron demands for informational materials and determine the attitudes and perceptions of Texas librarians toward various methods of interlibrary loan delivery.

TSLAC expects to make an award not to exceed $70,000.00.

A complete copy of the RFP will be posted on or before June 18, 2007 in the Texas Building and Procurement Commission, Electronic State Business Daily (ESBD) located at http://esbd.tbpc.state.tx.us/.

Please E-mail any questions with RFP #306-07-LRS-02 to: Purchase@tsl.state.tx.us. All questions must be received no later than June 21, 2007. TSLAC will post all questions and answers on June 28, 2007 by the close of the business day.

Contact: Charlotte Craig, Senior Purchaser

TRD-200702245
Edward Seidenberg
Assistant State Librarian
Texas State Library and Archives Commission
Filed: June 4, 2007

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Texas Lottery Commission

Instant Game Number 798 "World Poker Tour $100,000 Texas Hold'Em"

1.0 Name and Style of Game.

A. The name of Instant Game No. 798 is "WORLD POKER TOUR $100,000 TEXAS HOLD 'EM". The play style is "poker".

1.1 Price of Instant Ticket.

A. Tickets for Instant Game No. 798 shall be $10.00 per ticket.

1.2 Definitions in Instant Game No. 798.

A. Display Printing - That area of the instant game ticket outside of the area where the Overprint and Play Symbols appear.

B. Latex Overprint - The removable scratch-off covering over the Play Symbols on the front of the ticket.

C. Play Symbol - The printed data under the latex on the front of the instant ticket that is used to determine eligibility for a prize. Each Play Symbol is printed in Symbol font in black ink in positive except for dual-image games. The possible red play symbols are: A DIAMOND SYMBOL, K DIAMOND SYMBOL, Q DIAMOND SYMBOL, J DIAMOND SYMBOL, 10 DIAMOND SYMBOL, 9 DIAMOND SYMBOL, 8 DIAMOND SYMBOL, 7 DIAMOND SYMBOL, 6 DIAMOND SYMBOL, 5 DIAMOND SYMBOL, 4 DIAMOND SYMBOL, 3 DIAMOND SYMBOL, 2 DIAMOND SYMBOL, A HEART SYMBOL, K HEART SYMBOL, Q HEART SYMBOL, J HEART SYMBOL, 10 HEART SYMBOL, 9 HEART SYMBOL, 8 HEART SYMBOL, 7 HEART SYMBOL, 6 HEART SYMBOL, 5 HEART SYMBOL, 4 HEART SYMBOL, 3 HEART SYMBOL and 2 HEART SYMBOL. The possible black play symbols are: A SPADE SYMBOL, K SPADE SYMBOL, Q SPADE SYMBOL, J SPADE SYMBOL, 10 SPADE SYMBOL, 9 SPADE SYMBOL, 8 SPADE SYMBOL, 7 SPADE SYMBOL, 6 SPADE SYMBOL, 5 SPADE SYMBOL, 4 SPADE SYMBOL, 3 SPADE SYMBOL, 2 SPADE SYMBOL, A CLUB SYMBOL, K CLUB SYMBOL, Q CLUB SYMBOL, J CLUB SYMBOL, 10 CLUB SYMBOL, 9 CLUB SYMBOL, 8 CLUB SYMBOL, 7 CLUB SYMBOL, 6 CLUB SYMBOL, 5 CLUB SYMBOL, 4 CLUB SYMBOL, 3 CLUB SYMBOL, 2 CLUB SYMBOL, $10.00, $15.00, $20.00, $25.00, $50.00, $75.00, $100, $250, $500, $5,000, $100,000, MERCH and WPT.

D. Play Symbol Caption - the printed material appearing below each Play Symbol which explains the Play Symbol. One caption appears under each Play Symbol and is printed in caption font in black ink

in positive. The Play Symbol Caption which corresponds with and verifies each Play Symbol is as follows:

Figure 1: GAME NO. 798 - 1.2D

PLAY SYMBOL	CAPTION
A DIAMOND SYMBOL (red)	
K DIAMOND SYMBOL (red)	
Q DIAMOND SYMBOL (red)	
J DIAMOND SYMBOL(red)	
10 DIAMOND SYMBOL (red)	
9 DIAMOND SYMBOL (red)	
8 DIAMOND SYMBOL (red)	
7 DIAMOND SYMBOL (red)	
6 DIAMOND SYMBOL (red)	
5 DIAMOND SYMBOL(red)	
4 DIAMOND SYMBOL (red)	
3 DIAMOND SYMBOL (red)	
2 DIAMOND SYMBOL (red)	
A HEART SYMBOL (red)	
K HEART SYMBOL (red)	
Q HEART SYMBOL (red)	
J HEART SYMBOL (red)	
10 HEART SYMBOL (red)	
9 HEART SYMBOL (red)	
8 HEART SYMBOL (red)	
7 HEART SYMBOL (red)	
6 HEART SYMBOL (red)	
5 HEART SYMBOL (red)	
4 HEART SYMBOL (red)	
3 HEART SYMBOL (red)	
2 HEART SYMBOL (red)	
A SPADE SYMBOL (black)	
K SPADE SYMBOL (black)	
Q SPADE SYMBOL (black)	
J SPADE SYMBOL (black)	
10 SPADE SYMBOL (black)	
9 SPADE SYMBOL (black)	
8 SPADE SYMBOL (black)	
7 SPADE SYMBOL (black)	
6 SPADE SYMBOL (black)	
5 SPADE SYMBOL (black)	
4 SPADE SYMBOL (black)	
3 SPADE SYMBOL (black)	
2 SPADE SYMBOL (black)	
A CLUB SYMBOL (black)	
K CLUB SYMBOL (black)	
Q CLUB SYMBOL (black)	
J CLUB SYMBOL (black)	
10 CLUB SYMBOL (black)	
9 CLUB SYMBOL (black)	
8 CLUB SYMBOL (black)	

7 CLUB SYMBOL (black)	
6 CLUB SYMBOL (black)	
5 CLUB SYMBOL (black)	
4 CLUB SYMBOL (black)	
3 CLUB SYMBOL (black)	
2 CLUB SYMBOL (black)	
$10.00 (black)	TEN$
$15.00 (black)	FIFTN
$20.00 (black)	TWENTY
$25.00 (black)	TWY FIV
$50.00 (black)	FIFTY
$75.00 (black)	SVY FIV
$100 (black)	ONE HUND
$250 (black)	TWO FTY
$500 (black)	FIV HUND
$5,000 (black)	FIV THOU
$100,000 (black)	100 THOU
MERCH (black)	PACK
WPT (black)	TRIP

E. Retailer Validation Code - Three (3) letters found under the removable scratch-off covering in the play area, which retailers use to verify and validate instant winners. These three (3) small letters are for validation purposes and cannot be used to play the game. The possible validation codes are:

Figure 2: GAME NO. 798 - 1.2E

CODE	PRIZE
TEN	$10.00
FTN	$15.00
TWN	$20.00

Low-tier winning tickets use the required codes listed in Figure 2. Non-winning tickets and high-tier tickets use a non-required combination of the required codes listed in Figure 2 with the exception of ∅, which will only appear on low-tier winners and will always have a slash through it.

F. Serial Number - A unique 13 (thirteen) digit number appearing under the latex scratch-off covering on the front of the ticket. There is a boxed four (4) digit Security Number placed randomly within the Serial Number. The remaining nine (9) digits of the Serial Number are the Validation Number. The Serial Number is positioned beneath the bottom row of play data in the scratched-off play area. The Serial Number is for validation purposes and cannot be used to play the game. The format will be: 0000000000000.

G. Low-Tier Prize - A prize of $10.00, $15.00 or $20.00.

H. Mid-Tier Prize - A prize of $25.00, $50.00, $75.00, $100, $250, $500 or PACK.

I. High-Tier Prize - A prize of TRIP, $5,000 or $100,000.

J. Bar Code - A 22 (twenty-two) character interleaved two (2) of five (5) bar code which will include a three (3) digit game ID, the seven (7) digit pack number, the three (3) digit ticket number and the nine (9) digit Validation Number. The bar code appears on the back of the ticket.

K. Pack-Ticket Number - A 13 (thirteen) digit number consisting of the three (3) digit game number (798), a seven (7) digit pack number, and a three (3) digit ticket number. Ticket numbers start with 001 and end with 050 within each pack. The format will be: 798-0000001-001.

L. Pack - A pack of "WORLD POKER TOUR $100,000 TEXAS HOLD 'EM" Instant Game tickets contains 50 tickets, packed in plastic shrink-wrapping and fanfolded in pages of one (1). Ticket back 001 and 050 will both be exposed.

M. Non-Winning Ticket - A ticket which is not programmed to be a winning ticket or a ticket that does not meet all of the requirements of these Game Procedures, the State Lottery Act (Texas Government Code, Chapter 466), and applicable rules adopted by the Texas Lottery pursuant to the State Lottery Act and referenced in 16 TAC, Chapter 401.

N. Ticket or Instant Game Ticket, or Instant Ticket - A Texas Lottery "WORLD POKER TOUR $100,000 TEXAS HOLD 'EM" Instant Game No. 798 ticket.

2.0 Determination of Prize Winners. The determination of prize winners is subject to the general ticket validation requirements set forth in Texas Lottery Rule 401.302, Instant Game Rules, these Game Procedures, and the requirements set out on the back of each instant ticket. A prize winner in the "WORLD POKER TOUR $100,000 TEXAS HOLD 'EM" Instant Game is determined once the latex on the ticket

is scratched off to expose 50 (fifty) Play Symbols. At each table, use YOUR 2 CARDS and the COMMUNITY CARDS to make your best 5-card poker hand. Do the same with THEIR 2 CARDS. If YOUR best 5-card poker hand beats THEIR best 5-card poker hand at the same TABLE, the player wins the prize shown for that TABLE. Each TABLE uses one 52-card deck. There are no Wild Cards. No portion of the display printing nor any extraneous matter whatsoever shall be usable or playable as a part of the Instant Game.

2.1 Instant Ticket Validation Requirements.

A. To be a valid Instant Game ticket, all of the following requirements must be met:

1. Exactly 50 (fifty) Play Symbols must appear under the latex overprint on the front portion of the ticket;

2. Each of the Play Symbols must have a Play Symbol Caption underneath, unless specified, and each Play Symbol must agree with its Play Symbol Caption;

3. Each of the Play Symbols must be present in its entirety and be fully legible;

4. Each of the Play Symbols must be printed in black ink except for dual image games;

5. The ticket shall be intact;

6. The Serial Number, Retailer Validation Code and Pack-Ticket Number must be present in their entirety and be fully legible;

7. The Serial Number must correspond, using the Texas Lottery's codes, to the Play Symbols on the ticket;

8. The ticket must not have a hole punched through it, be mutilated, altered, unreadable, reconstituted or tampered with in any manner;

9. The ticket must not be counterfeit in whole or in part;

10. The ticket must have been issued by the Texas Lottery in an authorized manner;

11. The ticket must not have been stolen, nor appear on any list of omitted tickets or non-activated tickets on file at the Texas Lottery;

12. The Play Symbols, Serial Number, Retailer Validation Code and Pack-Ticket Number must be right side up and not reversed in any manner;

13. The ticket must be complete and not miscut, and have exactly 50 (fifty) Play Symbols under the latex overprint on the front portion of the ticket, exactly one Serial Number, exactly one Retailer Validation Code, and exactly one Pack-Ticket Number on the ticket;

14. The Serial Number of an apparent winning ticket shall correspond with the Texas Lottery's Serial Numbers for winning tickets, and a ticket with that Serial Number shall not have been paid previously;

15. The ticket must not be blank or partially blank, misregistered, defective or printed or produced in error;

16. Each of the 50 (fifty) Play Symbols must be exactly one of those described in Section 1.2.C of these Game Procedures.

17. Each of the 50 (fifty) Play Symbols on the ticket must be printed in the Symbol font and must correspond precisely to the artwork on file at the Texas Lottery; the ticket Serial Numbers must be printed in the Serial font and must correspond precisely to the artwork on file at the Texas Lottery; and the Pack-Ticket Number must be printed in the Pack-Ticket Number font and must correspond precisely to the artwork on file at the Texas Lottery;

18. The display printing on the ticket must be regular in every respect and correspond precisely to the artwork on file at the Texas Lottery; and

19. The ticket must have been received by the Texas Lottery by applicable deadlines.

B. The ticket must pass all additional validation tests provided for in these Game Procedures, the Texas Lottery's Rules governing the award of prizes of the amount to be validated, and any confidential validation and security tests of the Texas Lottery.

C. Any Instant Game ticket not passing all of the validation requirements is void and ineligible for any prize and shall not be paid. However, the Executive Director may, solely at the Executive Director's discretion, refund the retail sales price of the ticket. In the event a defective ticket is purchased, the only responsibility or liability of the Texas Lottery shall be to replace the defective ticket with another unplayed ticket in that Instant Game (or a ticket of equivalent sales price from any other current Instant Lottery game) or refund the retail sales price of the ticket, solely at the Executive Director's discretion.

2.2 Programmed Game Parameters.

A. Consecutive non-winning tickets will not have identical play data, spot for spot.

B. No duplicate non-winning prize symbols on a ticket.

C. A ticket may only win once in each table for a total of five possible wins on a ticket.

D. No duplicate tables, in any order, on any ticket.

E. Each table on a ticket will use a deck of fifty-two (52) cards.

F. Listed below is a Glossary of Terms for use in the patterns to follow: "Starting Hand" - The two (2) cards underneath the scratch-off coating marked "YOUR 2 CARDS," or underneath the Scratch-off coating marked "THEIR 2 CARDS". "Table" - Any of the five (5) play areas on each ticket. "Board" - The five (5) cards underneath the scratch-off coating marked "COMMUNITY CARDS". "Suit" - The Spades, Hearts, Diamonds and Clubs are the four (4) Suits. "Suited" - Any amount of cards where each card is of the same Suit (for example, 4 of Hearts + 5 of Hearts). "Non-suited" - Any amount of cards where at least one is of a different suit (for example, 4 of Hearts + 5 of Spades). "Sequential" - Any amount of cards that are connected (for example, 10 of Hearts; Jack of Hearts; Queen of Diamonds; King of Clubs; Ace of Spades). "Non-Sequential" - Any amount of cards that are not connected (for example, Ace of Hearts + Queen of Diamonds). "Pair" - Two (2) cards of the exact same rank (for example, Ace of Diamonds + Ace of Spades or 7 of Hearts + 7 of Clubs). "Three of a Kind" - Three (3) cards of the exact same rank. "Straight" - Five (5) non-suited cards in sequential order (for example, 2 of Clubs; 3 of Hearts; 4 of Diamonds; 5 of Spades; 6 of Diamonds). "Flush" - Five (5) non-sequential cards of the same suit (for example, 2 of Diamonds; 4 of Diamonds; 5 of Diamonds; Jack of Diamonds; King of Diamonds). "Full House" - Three (3) of a kind with a pair (for example, 4 of Diamonds; 4 of Clubs; 4 of Spades; 9 of Hearts; 9 of Diamonds). "Four of a Kind" - Four (4) cards of the exact same rank. "Straight Flush" - Five (5) suited and sequential cards, EXCEPT the highest five (5) sequential cards. "Royal Flush" - The highest five (5) suited and sequential cards (for example, 10 of Diamonds; Jack of Diamonds; Queen of Diamonds; King of Diamonds; Ace of Diamonds). "Final Hand" - The highest ranking five-card hand that uses the two (2) cards in either STARTING HAND with the five (5) cards on the Board.

G. Each and every Starting Hand (YOUR 2 CARDS or THEIR 2 CARDS) will come from one of the following groups: A. Any Pair B. Any Suited and Sequential two (2) cards C. Any Non-Suited and

Sequential or any Non-Suited and Non-Sequential Cards where BOTH cards are either a 10, Jack, Queen, King or Ace

H. The Suit or Suits used in one of the Starting Hands will NEVER match any of the Suit or Suits in the other Starting Hand for that table.

I. In any table, the two (2) starting Hands will never be of the same rank (for example, Jack of Hearts + 10 of Hearts vs. Jack of Diamonds + 10 of Clubs or 4 of Clubs + 4 of Diamonds vs. 4 of Hearts + 4 of Spades.

J. No Board will ever contain a Straight, Flush, Full House, Four of a Kind, Straight Flush or Royal Flush.

K. No Board will ever contain four (4) cards of the same suit.

L. Every Straight or Straight Flush will use the card ranks below. An Ace will never be used in a Straight or Straight Flush. 2, 3, 4, 5, 6 3, 4, 5, 6, 7 4, 5, 6, 7, 8 5, 6, 7, 8, 9 6, 7, 8, 9, 10 7, 8, 9, 10, Jack 8, 9, 10, Jack, Queen 9, 10, Jack, Queen, King

M. A Straight will never appear in the same table with a Straight Flush or a Royal Flush.

2.3 Procedure for Claiming Prizes.

A. To claim a "WORLD POKER TOUR $100,000 TEXAS HOLD 'EM" Instant Game prize of $10.00, $15.00, $20.00, $25.00, $50.00, $75.00, $100, $250, $500 or PACK, a claimant shall sign the back of the ticket in the space designated on the ticket and present the winning ticket to any Texas Lottery Retailer. The Texas Lottery Retailer shall verify the claim and, if valid, and upon presentation of proper identification, make payment of the amount due the claimant and physically void the ticket; provided that the Texas Lottery Retailer may, but is not, in some cases, required to pay a $25.00, 50.00, $75.00, $100, $250, $500 or PACK ticket. In the event the Texas Lottery Retailer cannot verify the claim, the Texas Lottery Retailer shall provide the claimant with a claim form and instruct the claimant on how to file a claim with the Texas Lottery. If the claim is validated by the Texas Lottery, a check shall be forwarded to the claimant in the amount due. In the event the claim is not validated, the claim shall be denied and the claimant shall be notified promptly. A claimant may also claim any of the above prizes under the procedure described in Section 2.3.B and Section 2.3.C of these Game Procedures.

B. To claim a "WORLD POKER TOUR $100,000 TEXAS HOLD 'EM" Instant Game prize of TRIP, $5,000 or $100,000, the claimant must sign the winning ticket and present it at one of the Texas Lottery's Claim Centers. If the claim is validated by the Texas Lottery, payment will be made to the bearer of the validated winning ticket for that prize upon presentation of proper identification. When paying a prize of $600 or more, the Texas Lottery shall file the appropriate income reporting form with the Internal Revenue Service (IRS) and shall withhold federal income tax at a rate set by the IRS if required. In the event that the claim is not validated by the Texas Lottery, the claim shall be denied and the claimant shall be notified promptly.

C. As an alternative method of claiming a "WORLD POKER TOUR $100,000 TEXAS HOLD 'EM" Instant Game prize, the claimant must sign the winning ticket, thoroughly complete a claim form, and mail both to: Texas Lottery Commission, Post Office Box 16600, Austin, Texas 78761-6600. The risk of sending a ticket remains with the claimant. In the event that the claim is not validated by the Texas Lottery, the claim shall be denied and the claimant shall be notified promptly.

D. Prior to payment by the Texas Lottery of any prize, the Texas Lottery shall deduct a sufficient amount from the winnings of a person who has been finally determined to be:

1. delinquent in the payment of a tax or other money collected by the Comptroller, the Texas Workforce Commission, or Texas Alcoholic Beverage Commission;

2. delinquent in making child support payments administered or collected by the Attorney General; or

3. delinquent in reimbursing the Texas Health and Human Services Commission for a benefit granted in error under the food stamp program or the program of financial assistance under Chapter 31, Human Resources Code;

4. in default on a loan made under Chapter 52, Education Code; or

5. in default on a loan guaranteed under Chapter 57, Education Code.

E. If a person is indebted or owes delinquent taxes to the State, other than those specified in the preceding paragraph, the winnings of a person shall be withheld until the debt or taxes are paid.

2.4 Allowance for Delay of Payment. The Texas Lottery may delay payment of the prize pending a final determination by the Executive Director, under any of the following circumstances:

A. if a dispute occurs, or it appears likely that a dispute may occur, regarding the prize;

B. if there is any question regarding the identity of the claimant;

C. if there is any question regarding the validity of the ticket presented for payment; or

D. if the claim is subject to any deduction from the payment otherwise due, as described in Section 2.3.D of these Game Procedures. No liability for interest for any delay shall accrue to the benefit of the claimant pending payment of the claim.

2.5 Payment of Prizes to Persons Under 18. If a person under the age of 18 years is entitled to a cash prize of less than $600 from the "WORLD POKER TOUR $100,000 TEXAS HOLD 'EM" Instant Game, the Texas Lottery shall deliver to an adult member of the minor's family or the minor's guardian a check or warrant in the amount of the prize payable to the order of the minor.

2.6 If a person under the age of 18 years is entitled to a cash prize of more than $600 from the "WORLD POKER TOUR $100,000 TEXAS HOLD 'EM" Instant Game, the Texas Lottery shall deposit the amount of the prize in a custodial bank account, with an adult member of the minor's family or the minor's guardian serving as custodian for the minor.

2.7 Instant Ticket Claim Period. All Instant Game prizes must be claimed within 180 days following the end of the Instant Game or within the applicable time period for certain eligible military personnel as set forth in Texas Government Code Section 466.408. Any prize not claimed within that period, and in the manner specified in these Game Procedures and on the back of each ticket, shall be forfeited.

2.8 Disclaimer. The number of prizes in a game is approximate based on the number of tickets ordered. The number of actual prizes available in a game may vary based on number of tickets manufactured, testing, distribution, sales and number of prizes claimed. An Instant Game ticket may continue to be sold even when all the top prizes have been claimed.

3.0 Instant Ticket Ownership.

A. Until such time as a signature is placed upon the back portion of an Instant Game ticket in the space designated, a ticket shall be owned by the physical possessor of said ticket. When a signature is placed on the back of the ticket in the space designated, the player whose signature appears in that area shall be the owner of the ticket and shall be entitled

to any prize attributable thereto. Notwithstanding any name or names submitted on a claim form, the Executive Director shall make payment to the player whose signature appears on the back of the ticket in the space designated. If more than one name appears on the back of the ticket, the Executive Director will require that one of those players whose name appears thereon be designated by such players to receive payment.

B. The Texas Lottery shall not be responsible for lost or stolen Instant Game tickets and shall not be required to pay on a lost or stolen Instant Game ticket.

4.0 Number and Value of Instant Prizes. There will be approximately 4,080,000 tickets in the Instant Game No. 798. The approximate number and value of prizes in the game are as follows:

Figure 3: GAME NO. 798 - 4.0

Prize Amount	Approximate Number of Winners*	Approximate Odds are 1 in**
$10	652,800	6.25
$15	326,400	12.50
$20	163,200	25.00
$25	81,600	50.00
$50	81,600	50.00
$75	26,690	152.87
$100	7,480	545.45
$250	3,060	1,333.33
$500	1,292	3,157.89
PACK	5,130	795.32
TRIP	4	1,020,000.00
$5,000	68	60,000.00
$100,000	6	680,000.00

*The number of prizes in a game is approximate based on the number of tickets ordered. The number of actual prizes available in a game may vary based on number of tickets manufactured, testing, distribution, sales and number of prizes claimed.

**The overall odds of winning a prize are 1 in 3.02. The individual odds of winning for a particular prize level may vary based on sales, distribution, testing, and number of prizes claimed.

A. The actual number of tickets in the game may be increased or decreased at the sole discretion of the Texas Lottery Commission.

5.0 End of the Instant Game. The Executive Director may, at any time, announce a closing date (end date) for the Instant Game No. 798 without advance notice, at which point no further tickets in that game may be sold.

6.0 Governing Law. In purchasing an Instant Game ticket, the player agrees to comply with, and abide by, these Game Procedures for Instant Game No. 798, the State Lottery Act (Texas Government Code, Chapter 466), applicable rules adopted by the Texas Lottery pursuant to the State Lottery Act and referenced in 16 TAC, Chapter 401, and all final decisions of the Executive Director.

TRD-200702265
Kimberly L. Kiplin
General Counsel
Texas Lottery Commission
Filed: June 6, 2007

♦ ♦ ♦

Instant Game Number 840 "Big Money Bingo"

1.0 Name and Style of Game.

A. The name of Instant Game No. 840 is "BIG MONEY BINGO". The play style is "bingo with multiplier".

1.1 Price of Instant Ticket.

A. Tickets for Instant Game No. 840 shall be $5.00 per ticket.

1.2 Definitions in Instant Game No. 840.

A. Display Printing--That area of the instant game ticket outside of the area where the Overprint and Play Symbols appear.

B. Latex Overprint--The removable scratch-off covering over the Play Symbols on the front of the ticket.

C. Play Symbol--The printed data under the latex on the front of the instant ticket that is used to determine eligibility for a prize. Each Play Symbol is printed in Symbol font in black ink in positive except for dual-image games. The possible black play symbols are: B01, B02, B03, B04, B05, B06, B07, B08, B09, B10, B11, B12, B13, B14, B15, I16, I17, I18, I19, I20, I21, I22, I23, I24, I25, I26, I27, I28, I29, I30, N31, N32, N33, N34, N35, N36, N37, N38, N39, N40, N41, N42, N43, N44, N45, G46, G47, G48, G49, G50, G51, G52, G53, G54, G55, G56, G57, G58, G59, G60, O61, O62, O63, O64, O65, O66, O67, O68, O69, O70, O71, O72, O73, O74, O75, 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67,

68, 69, 70, 71, 72, 73, 74, 75, FREE, 1X SYMBOL, 2X SYMBOL, 3X SYMBOL, and 5X SYMBOL.

D. Play Symbol Caption--the printed material appearing below each Play Symbol which explains the Play Symbol. One caption appears under each Play Symbol and is printed in caption font in black ink in positive. The Play Symbol Caption which corresponds with and verifies each Play Symbol is as follows:

Figure 1: GAME NO. 840 - 1.2D

PLAY SYMBOL	CAPTION
B01	
B02	
B03	
B04	
B05	
B06	
B07	
B08	
B09	
B10	
B11	
B12	
B13	
B14	
B15	
I16	
I17	
I18	
I19	
I20	
I21	
I22	
I23	
I24	
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66	
67	
68	
69	

70	
71	
72	
73	
74	
75	
FREE	
1X SYMBOL	PRIZE
2X SYMBOL	PRIZE
3X SYMBOL	PRIZE
5X SYMBOL	PRIZE

E. Retailer Validation Code--Three (3) letters found under the removable scratch-off covering in the play area, which retailers use to verify and validate instant winners. These three (3) small letters are for validation purposes and cannot be used to play the game. The possible validation codes are:

Figure 2: GAME NO. 840 - 1.2E

CODE	PRIZE
FIV	$5.00
TEN	$10.00
FTN	$15.00
TWN	$20.00

Low-tier winning tickets use the required codes listed in Figure 2. Non-winning tickets and high-tier tickets use a non-required combination of the required codes listed in Figure 2 with the exception of ∅, which will only appear on low-tier winners and will always have a slash through it.

F. Serial Number--A unique 13 (thirteen) digit number appearing under the latex scratch-off covering on the front of the ticket. There is a boxed four (4) digit Security Number placed randomly within the Serial Number. The remaining nine (9) digits of the Serial Number are the Validation Number. The Serial Number is positioned beneath the bottom row of play data in the scratched-off play area. The format will be: 0000000000000.

G. Low-Tier Prize--A prize of $5.00, $10.00, $15.00, or $20.00.

H. Mid-Tier Prize-- A prize of $25.00, $30.00, $40.00, $50.00, $75.00, $100, $200, or $500.

I. High-Tier Prize--A prize of $1,000, $2,000, $5,000, $20,000, or $50,000.

J. Bar Code--A 22 (twenty-two) character interleaved two (2) of five (5) bar code which will include a three (3) digit game ID, the seven (7) digit pack number, the three (3) digit ticket number, and the nine (9) digit Validation Number. The bar code appears on the back of the ticket.

K. Pack-Ticket Number--A 13 (thirteen) digit number consisting of the three (3) digit game number (840), a seven (7) digit pack number, and a three (3) digit ticket number. Ticket numbers start with 001 and end with 075 within each pack. The format will be: 840-0000001-001.

L. Pack--A pack of "BIG MONEY BINGO" Instant Game tickets contains 75 tickets, packed in plastic shrink-wrapping and fanfolded in pages of one (1). Ticket 001 will be shown on the front of the pack; the back of ticket 075 will be revealed on the back of the pack. All packs will be tightly shrink-wrapped. There will be no breaks between the tickets in a pack. Every other book will reverse, i.e., reverse order will be : the back of ticket 001 will be shown on the front of the pack and the front of ticket 075 will be shown on the back of the pack.

M. Non-Winning Ticket--A ticket which is not programmed to be a winning ticket or a ticket that does not meet all of the requirements of these Game Procedures, the State Lottery Act (Texas Government Code, Chapter 466), and applicable rules adopted by the Texas Lottery pursuant to the State Lottery Act and referenced in 16 TAC Chapter 401.

N. Ticket or Instant Game Ticket, or Instant Ticket--A Texas Lottery "BIG MONEY BINGO" Instant Game No. 840 ticket.

2.0 Determination of Prize Winners. The determination of prize winners is subject to the general ticket validation requirements set forth in Texas Lottery Rule, §401.302, Instant Game Rules; these Game Procedures; and the requirements set out on the back of each instant ticket. A prize winner in the "BIG MONEY BINGO" Instant Game is determined once the latex on the ticket is scratched off to expose 181 (one hundred eighty-one) play symbols. The player must scratch off the CALLER'S CARD area to reveal 24 (twenty-four) Bingo Numbers and six (6) Bonus Numbers. The player must scratch all the Bingo Numbers on CARDS 1 through 6 that match the Bingo Numbers and Bonus Numbers on the CALLER'S CARD. Each CARD has a corresponding prize legend. Players win by matching those same numbers on the six Player's Cards. If the player finds a diagonal, vertical or horizontal straight line, the four corners of the grid, or an X pattern, they win a prize according to the legend of the respective playing grid. Examples of play: If a player matches all bingo numbers plus the Free Space in a complete horizontal, vertical, or diagonal line pattern in any one card, the player wins prize according to the legend of the respective playing card. If the player matches all bingo numbers in all four (4) corners pattern in any one card, the player wins prize according to the legend of the respective playing card. If the player matches all bingo numbers plus Free Space to make a complete "X" pattern in any one card, the

player wins prize according to the legend of the respective playing card. In the PRIZE MUTIPLIER play area, if a player reveals a "2X", "3X", or "5X" play symbol, any prize won on Cards 1 through 6 is multiplied by that amount. The player can win up to six times on any ticket but only once on each "card". No portion of the display printing nor any extraneous matter whatsoever shall be usable or playable as a part of the Instant Game.

2.1 Instant Ticket Validation Requirements.

A. To be a valid Instant Game ticket, all of the following requirements must be met:

1. Exactly 181 (one hundred eighty-one) Play Symbols must appear under the latex overprint on the front portion of the ticket;

2. Each of the Play Symbols must have a Play Symbol Caption underneath, unless specified, and each Play Symbol must agree with its Play Symbol Caption;

3. Each of the Play Symbols must be present in its entirety and be fully legible;

4. Each of the Play Symbols must be printed in black ink except for dual image games;

5. The ticket shall be intact;

6. The Serial Number, Retailer Validation Code, and Pack-Ticket Number must be present in their entirety and be fully legible;

7. The Serial Number must correspond, using the Texas Lottery's codes, to the Play Symbols on the ticket;

8. The ticket must not have a hole punched through it, be mutilated, altered, unreadable, reconstituted, or tampered with in any manner;

9. The ticket must not be counterfeit in whole or in part;

10. The ticket must have been issued by the Texas Lottery in an authorized manner;

11. The ticket must not have been stolen nor appear on any list of omitted tickets or non-activated tickets on file at the Texas Lottery;

12. The Play Symbols, Serial Number, Retailer Validation Code, and Pack-Ticket Number must be right side up and not reversed in any manner;

13. The ticket must be complete and not miscut and have exactly 181 (one hundred eighty-one) Play Symbols under the latex overprint on the front portion of the ticket, exactly one Serial Number, exactly one Retailer Validation Code, and exactly one Pack-Ticket Number on the ticket;

14. The Serial Number of an apparent winning ticket shall correspond with the Texas Lottery's Serial Numbers for winning tickets, and a ticket with that Serial Number shall not have been paid previously;

15. The ticket must not be blank or partially blank, misregistered, defective, or printed or produced in error;

16. Each of the 181 (one hundred eighty-one) Play Symbols must be exactly one of those described in Section 1.2.C of these Game Procedures.

17. Each of the 181 (one hundred eighty-one) Play Symbols on the ticket must be printed in the Symbol font and must correspond precisely to the artwork on file at the Texas Lottery; the ticket Serial Numbers must be printed in the Serial font and must correspond precisely to the artwork on file at the Texas Lottery; and the Pack-Ticket Number must be printed in the Pack-Ticket Number font and must correspond precisely to the artwork on file at the Texas Lottery;

18. The display printing on the ticket must be regular in every respect and correspond precisely to the artwork on file at the Texas Lottery; and

19. The ticket must have been received by the Texas Lottery by applicable deadlines.

B. The ticket must pass all additional validation tests provided for in these Game Procedures, the Texas Lottery's Rules governing the award of prizes of the amount to be validated, and any confidential validation and security tests of the Texas Lottery.

C. Any Instant Game ticket not passing all of the validation requirements is void and ineligible for any prize and shall not be paid. However, the Executive Director may, solely at the Executive Director's discretion, refund the retail sales price of the ticket. In the event a defective ticket is purchased, the only responsibility or liability of the Texas Lottery shall be to replace the defective ticket with another unplayed ticket in that Instant Game (or a ticket of equivalent sales price from any other current Instant Lottery game) or refund the retail sales price of the ticket, solely at the Executive Director's discretion.

2.2 Programmed Game Parameters.

A. Consecutive non-winning tickets within in a pack will not have identical patterns.

B. A ticket will win as indicated by the prize structure.

C. A ticket can win up to six times and only once per Card.

D. There will never be more than one win on a single player's Card.

E. The highest prize won per card will be paid.

F. No duplicate numbers will appear on the CALLER'S CARD.

G. No duplicate numbers will appear on each individual player's Card.

H. The number range used for each letter will be as follows: B: 01 - 15; I: 16 - 30; N: 31 - 45; G: 46 - 60; O: 61 - 75.

I. Each player's Card on the same ticket must be unique.

J. The 24 CALLER'S CARD numbers and 6 BONUS NUMBERS will match 53 to 83 numbers per ticket.

K. The 'near wins' are to be distributed approximately equally in the six player's Cards.

L. There will be at least one (1) 'near win' on each of the six (6) player's Cards on each non-winning ticket.

M. A 'near win' is one number short of a complete horizontal, vertical, diagonal line or 4 corners, except for the 'X' where there are two numbers less, one in each diagonal line (one of which must be a corner).

N. The play symbols "1X", "2X", "3X", and "5X" will be used in the PRIZE MULTIPLIER area.

O. The play symbols will be used on winning tickets only as per the prize structure.

P. The "1X" symbol will be used on winning tickets when the prize is not multiplied, as per the prize structure.

2.3 Procedure for Claiming Prizes.

A. To claim a "BIG MONEY BINGO" Instant Game prize of $5.00, $10.00, $15.00, $20.00, $25.00, $30.00, $40.00, $50.00, $75.00, $100, $200, or $500, a claimant shall sign the back of the ticket in the space designated on the ticket and present the winning ticket to any Texas Lottery Retailer. The Texas Lottery Retailer shall verify the claim and, if valid, and upon presentation of proper identification, make payment of the amount due the claimant and physically void the ticket; provided

that the Texas Lottery Retailer may, but is not, in some cases, required to pay a $25.00, $30.00, $40.00, $50.00, $75.00, $100, $200, or $500 ticket. In the event the Texas Lottery Retailer cannot verify the claim, the Texas Lottery Retailer shall provide the claimant with a claim form and instruct the claimant on how to file a claim with the Texas Lottery. If the claim is validated by the Texas Lottery, a check shall be forwarded to the claimant in the amount due. In the event the claim is not validated, the claim shall be denied and the claimant shall be notified promptly. A claimant may also claim any of the above prizes under the procedure described in Section 2.3.B and Section 2.3.C of these Game Procedures.

B. To claim a "BIG MONEY BINGO" Instant Game prize of $1,000, $2,000, $5,000, $20,000, or $50,000, the claimant must sign the winning ticket and present it at one of the Texas Lottery's Claim Centers. If the claim is validated by the Texas Lottery, payment will be made to the bearer of the validated winning ticket for that prize upon presentation of proper identification. When paying a prize of $600 or more, the Texas Lottery shall file the appropriate income reporting form with the Internal Revenue Service (IRS) and shall withhold federal income tax at a rate set by the IRS if required. In the event that the claim is not validated by the Texas Lottery, the claim shall be denied and the claimant shall be notified promptly.

C. As an alternative method of claiming a "BIG MONEY BINGO" Instant Game prize, the claimant must sign the winning ticket, thoroughly complete a claim form, and mail both to: Texas Lottery Commission, Post Office Box 16600, Austin, Texas 78761-6600. The risk of sending a ticket remains with the claimant. In the event that the claim is not validated by the Texas Lottery, the claim shall be denied and the claimant shall be notified promptly.

D. Prior to payment by the Texas Lottery of any prize, the Texas Lottery shall deduct a sufficient amount from the winnings of a person who has been finally determined to be:

1. delinquent in the payment of a tax or other money collected by the Comptroller of Public Accounts, the Texas Workforce Commission, or Texas Alcoholic Beverage Commission;

2. delinquent in making child support payments administered or collected by the Office of Attorney General; or

3. delinquent in reimbursing the Texas Health and Human Services Commission for a benefit granted in error under the food stamp program or the program of financial assistance under Chapter 31, Human Resources Code;

4. in default on a loan made under Chapter 52, Education Code; or

5. in default on a loan guaranteed under Chapter 57, Education Code.

E. If a person is indebted or owes delinquent taxes to the State, other than those specified in the preceding paragraph, the winnings of a person shall be withheld until the debt or taxes are paid.

2.4 Allowance for Delay of Payment. The Texas Lottery may delay payment of the prize pending a final determination by the Executive Director, under any of the following circumstances:

A. if a dispute occurs, or it appears likely that a dispute may occur, regarding the prize;

B. if there is any question regarding the identity of the claimant;

C. if there is any question regarding the validity of the ticket presented for payment; or

D. if the claim is subject to any deduction from the payment otherwise due, as described in Section 2.3.D of these Game Procedures. No liability for interest for any delay shall accrue to the benefit of the claimant pending payment of the claim.

2.5 Payment of Prizes to Persons Under 18. If a person under the age of 18 years is entitled to a cash prize of less than $600 from the "BIG MONEY BINGO" Instant Game, the Texas Lottery shall deliver to an adult member of the minor's family or the minor's guardian a check or warrant in the amount of the prize payable to the order of the minor.

2.6 If a person under the age of 18 years is entitled to a cash prize of more than $600 from the "BIG MONEY BINGO" Instant Game, the Texas Lottery shall deposit the amount of the prize in a custodial bank account, with an adult member of the minor's family, or the minor's guardian serving as custodian for the minor.

2.7 Instant Ticket Claim Period. All Instant Game prizes must be claimed within 180 days following the end of the Instant Game or within the applicable time period for certain eligible military personnel as set forth in Texas Government Code, §466.408. Any prize not claimed within that period and in the manner specified in these Game Procedures and on the back of each ticket, shall be forfeited.

2.8 Disclaimer. The number of prizes in a game is approximate based on the number of tickets ordered. The number of actual prizes available in a game may vary based on number of tickets manufactured, testing, distribution, sales, and number of prizes claimed. An Instant Game ticket may continue to be sold even when all the top prizes have been claimed.

3.0 Instant Ticket Ownership.

A. Until such time as a signature is placed upon the back portion of an Instant Game ticket in the space designated, a ticket shall be owned by the physical possessor of said ticket. When a signature is placed on the back of the ticket in the space designated, the player whose signature appears in that area shall be the owner of the ticket and shall be entitled to any prize attributable thereto. Notwithstanding any name or names submitted on a claim form, the Executive Director shall make payment to the player whose signature appears on the back of the ticket in the space designated. If more than one name appears on the back of the ticket, the Executive Director will require that one of those players whose name appears thereon be designated by such players to receive payment.

B. The Texas Lottery shall not be responsible for lost or stolen Instant Game tickets and shall not be required to pay on a lost or stolen Instant Game ticket.

4.0 Number and Value of Instant Prizes. There will be approximately 8,040,000 tickets in the Instant Game No. 840. The approximate number and value of prizes in the game are as follows:

Figure 3: GAME NO. 840 - 4.0

Prize Amount	Approximate Number of Winners*	Approximate Odds are 1 in**
$5	1,072,000	7.50
$10	536,000	15.00
$15	321,600	25.00
$20	107,200	75.00
$25	72,360	111.11
$30	40,200	200.00
$40	23,450	342.86
$50	28,140	285.71
$75	14,070	571.43
$100	6,700	1,200.00
$200	5,025	1,600.00
$500	1,943	4,137.93
$1,000	28	287,142.86
$2,000	14	574,285.71
$5,000	17	472,941.18
$20,000	7	1,148,571.43
$50,000	6	1,340,000.00

*The number of prizes in a game is approximate based on the number of tickets ordered. The number of actual prizes available in a game may vary based on number of tickets manufactured, testing, distribution, sales and number of prizes claimed.

**The overall odds of winning a prize are 1 in 3.61. The individual odds of winning for a particular prize level may vary based on sales, distribution, and number of prized claimed.

A. The actual number of tickets in the game may be increased or decreased at the sole discretion of the Texas Lottery Commission.

5.0 End of the Instant Game. The Executive Director may, at any time, announce a closing date (end date) for the Instant Game No. 840 without advance notice; at which point, no further tickets in that game may be sold.

6.0 Governing Law. In purchasing an Instant Game ticket, the player agrees to comply with, and abide by, these Game Procedures for Instant Game No. 840; the State Lottery Act (Texas Government Code, Chapter 466); applicable rules adopted by the Texas Lottery pursuant to the State Lottery Act and referenced in 16 TAC Chapter 401; and all final decisions of the Executive Director.

TRD-200702244
Kimberly L. Kiplin
General Counsel
Texas Lottery Commission
Filed: June 4, 2007

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North Central Texas Council of Governments

Notice of Consultant Contract Award

Pursuant to the provisions of Government Code, Chapter 2254, the North Central Texas Council of Governments publishes this notice of consultant contract award. The consultant proposal request appeared in the March 2, 2007, issue of the *Texas Register* (32 TexReg 1153). The selected consultant will perform technical and professional work to Collect and Analyze Traffic Data on Limited-Access Highways in the Dallas-Fort Worth Metropolitan Area Via Remote Sensing.

The consultant selected for this project is Skycomp Incorporated., 5999 Harper's Farm Road, #E-225, Columbia, MD 21044. The maximum amount of this contract is $355,000.

TRD-200702247
R. Michael Eastland
Executive Director
North Central Texas Council of Governments
Filed: June 5, 2007

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Public Utility Commission of Texas

Notice of Application for a Certificate to Provide Retail Electric Service

Notice is given to the public of the filing with the Public Utility Commission of Texas of an application on May 31, 2007, for retail electric provider (REP) certification, pursuant to §§39.101 - 39.109 of the Public Utility Regulatory Act (PURA).

Docket Title and Number: Application of Consulting Groups Network, LLC for Retail Electric Provider (REP) Certification, Docket Number 34363 before the Public Utility Commission of Texas.

Applicant's requested service area by geography includes the entire State of Texas.

Persons wishing to comment upon the action sought should contact the Public Utility Commission of Texas by mail at P.O. Box 13326, Austin, Texas 78711-3326, or by phone at (512) 936-7120 or toll free at 1-888-782-8477 no later than June 22, 2007. Hearing and speech-impaired individuals with text telephone (TTY) may contact the commission at (512) 936-7136 or toll free at 1-800-735-2989. All comments should reference Docket Number 34363.

TRD-200702249
Adriana A. Gonzales
Rules Coordinator
Public Utility Commission of Texas
Filed: June 5, 2007

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Notice of Application for Amendment to Certificated Service Area Boundary

Notice is given to the public of an application filed on May 29, 2007 with the Public Utility Commission of Texas for an amendment to a certificated service area boundary.

Docket Style and Number: Application of AT&T Texas to amend a Certificate of Convenience and Necessity to amend the Service Area Boundaries between the Crandall and Forney Exchanges. Docket Number 34349.

The Application: The minor boundary amendment is being filed to transfer a small portion of the Crandall Exchange to the Forney Exchange of AT&T Texas to accommodate an addition to an existing development in the Forney Exchange. The proposed change will keep the development from being served by two exchanges.

Persons wishing to comment on the action sought or intervene should contact the Public Utility Commission of Texas by June 22, 2007, by mail at P.O. Box 13326, Austin, Texas 78711-3326, or by phone at (512) 936-7120 or toll-free at 1-888-782-8477. Hearing and speech-impaired individuals with text telephone (TTY) may contact the commission at (512) 936-7136 or use Relay Texas (toll-free) 1-800-735-2989. All comments should reference Docket Number 34349.

TRD-200702154
Adriana A. Gonzales
Rules Coordinator
Public Utility Commission of Texas
Filed: June 1, 2007

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Notice of Application for Amendments to Service Provider Certificates of Operating Authority

On June 1, 2007, OnFiber Carrier Services, Inc. and Qwest Communications Corporation filed an application with the Public Utility Commission of Texas (commission) to amend their service provider certificates of operating authority (SPCOAs) granted in SPCOA Certificate Numbers 60363 and 60367. The Applicants intend to reflect consolidation, relinquishment of SPCOA held by OnFiber Carrier Service, Inc., and to reflect a change in service area and corporate restructuring.

The Application: Application of OnFiber Carrier Services, Inc., and Qwest Communications Corporation for Amendments to their Service Provider Certificates of Operating Authority, Docket Number 34374.

Persons wishing to comment on the action sought should contact the Public Utility Commission of Texas by mail at P.O. Box 13326, Austin, Texas 78711-3326, or by phone at (512) 936-7120 or toll free at 1-888-782-8477 no later than June 27, 2007. Hearing and speech-impaired individuals with text telephones (TTY) may contact the commission at (512) 936-7136 or toll free at 1-800-735-2989. All comments should reference Docket Number 34374.

TRD-200702256
Adriana A. Gonzales
Rules Coordinator
Public Utility Commission of Texas
Filed: June 5, 2007

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Notice of Application for Designation as an Eligible Telecommunications Carrier and Eligible Telecommunications Provider

Notice is given to the public of an application filed with the Public Utility Commission of Texas on June 1, 2007, for designation as an eligible telecommunications provider (ETP) and eligible telecommunications carrier (ETC) pursuant to P.U.C. Substantive Rule §26.417 and §26.418, respectively.

Docket Title and Number: Application of Talk Now Telco for Designation as an Eligible Telecommunications Carrier (ETC) and as an Eligible Telecommunications Provider (ETP) Docket Number 34371.

The Application: The company is requesting ETC/ETP designation in order to be eligible to receive federal and state universal service funding to assist it in providing universal service in Texas. Pursuant to 47 U.S.C. §214(e) and PURA §56.023, the commission designates qualifying common carriers as ETCs and ETPs for service areas set forth by the commission. Talk Now Telco seeks ETC/ETP designation in the study area of AT&T, a non-rural incumbent local exchange carrier. The Company holds Service Provider Certificate of Operating Authority Number 60753.

Persons who wish to comment upon the action sought should contact the Public Utility Commission of Texas by June 27, 2007. Requests for further information should be mailed to the Public Utility Commission of Texas, P.O. Box 13326, Austin, Texas 78711-3326, or you may call the Public Utility Commission's Customer Protection Division at (512) 936-7120 or (888) 782-8477. Hearing and speech-impaired individuals with text telephones (TTY) may contact the commission at (512) 936-7136 or use Relay Texas (800) 735-2989 to reach the commission's toll free number (888) 782-8477. All comments should reference Docket Number 34371.

TRD-200702255
Adriana A. Gonzales
Rules Coordinator
Public Utility Commission of Texas
Filed: June 5, 2007

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Notice of Application for Relinquishment of a Service Provider Certificate of Operating Authority

On May 31, 2007, Qwest Interprise America, Inc. filed an application with the Public Utility Commission of Texas (commission) to relinquish its service provider certificate of operating authority (SPCOA) granted in SPCOA Certificate Number 60121. Applicant intends to relinquish its certificate.

The Application: Application of Qwest Interprise America, Inc. to Relinquish its Service Provider Certificate of Operating Authority, Docket Number 34364.

Persons wishing to comment on the action sought should contact the Public Utility Commission of Texas by mail at P.O. Box 13326, Austin, Texas 78711-3326, or by phone at (512) 936-7120 or toll free at 1-888-782-8477 no later than June 20, 2007. Hearing and speech-impaired individuals with text telephones (TTY) may contact the commission at (512) 936-7136 or toll free at 1-800-735-2989. All comments should reference Docket Number 34364.

TRD-200702260
Adriana A. Gonzales
Rules Coordinator
Public Utility Commission of Texas
Filed: June 5, 2007

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Notice of Application for Sale, Transfer, or Merger

Notice is given to the public of an application for sale, transfer, or merger filed with the Public Utility Commission of Texas on May 31, 2007, pursuant to the Public Utility Regulatory Act, Texas Utilities Code Annotated §14.001 and §37.154 (Vernon 1998 & Supp. 2006) (PURA).

Docket Style and Number: Application of EnergyCo, LLC for Approval of Acquisition of Generation Facility Pursuant to PURA §39.158, Docket Number 34369.

The Application: EnergyCo, LLC (EnergyCo) filed an application for approval of acquisition of a generating facility currently owned by CoGen Lyondell, Inc. (CoGen), a wholly-owned indirect subsidiary of Dynegy Holdings, Inc. (Dynegy). As part of the transaction, Dynegy will convert CoGen from a Texas corporation to a limited liability company to be named CoGen Lyondell, LLC (CoGen LLC). At the close of the transaction, EnergyCo will purchase all of the issued and outstanding membership interests of CoGen.

EnergyCo is currently affiliated with Altura Power, LP (Altura), which owns, Twin Oaks, a 306 MW generating facility located in Robertson County, Texas and delivers electricity in the Electric Reliability Council of Texas (ERCOT) region. EnergyCo is jointly owned by PNM Resources, Inc. (PNM Resources) and ECJV Holdings, LLC (ECJV Holdings), which each hold a 50% interest. On or about June 1, 2007, PNM Resources will contribute Altura to EnergyCo.

The contribution was announced in PNM Resources' definitive proxy statement filed with the Securities and Exchange Commission on April 12, 2007.

Persons who wish to intervene in the proceeding or comment upon the action sought should contact the Public Utility Commission of Texas, P.O. Box 13326, Austin, Texas 78711-3326, or call the Commission's Office of Customer Protection at (512) 936-7120 or (888) 782-8477. Hearing- and speech-impaired individuals with text telephones (TTY) may contact the Commission at (512) 936-7136 or use Relay Texas (toll-free) 1-800-735-2989. All correspondence should refer to Docket Number 34369.

TRD-200702250
Adriana A. Gonzales
Rules Coordinator
Public Utility Commission of Texas
Filed: June 5, 2007

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Texas Department of Transportation

Request for Proposal for Aviation Engineering Services

Kimble County, through its agent the Texas Department of Transportation (TxDOT), intends to engage an aviation professional engineering firm for services pursuant to Government Code, Chapter 2254, Subchapter A. TxDOT Aviation Division will solicit and receive proposals for professional aviation engineering design services as described in this notice.

Airport Sponsor: Kimble County, Kimble County Airport, TxDOT CSJ No.: 0707JNCTN.

Scope: Provide engineering/design services for site development and associated appurtenances for a pre-engineered metal aircraft hangar building system, pavement, and drainage improvements at the Kimble County Airport.

The DBE goal is set at **6%**. TxDOT Project Manager is Megan Caffall.

To assist in your proposal preparation the most recent Airport Layout Plan, 5010 drawing, and project narrative are available online by selecting "Kimble County Airport" at:

www.dot.state.tx.us/avn/avninfo/notice/consult/index.htm

Interested firms shall utilize the latest version of Form AVN-550, titled "Aviation Engineering Services Proposal." The form may be requested from TxDOT, Aviation Division, 125 East 11th Street, Austin, Texas 78701-2483, phone number, 1-800-68-PILOT (74568). The form may be e-mailed by request or downloaded from the TxDOT web site at:

www.dot.state.tx.us/services/aviation/consultant.htm

The form may not be altered in any way. All printing must be in black on white paper, except for the optional illustration page. Firms must carefully follow the instructions provided on each page of the form. Proposals may not exceed the number of pages in the proposal format. The proposal format consists of seven pages of data plus two optional pages consisting of an illustration page and a proposal summary page. Proposals shall be stapled but not bound in any other fashion. PROPOSALS WILL NOT BE ACCEPTED IN ANY OTHER FORMAT. ATTENTION: To ensure utilization of the latest version of Form AVN-550, firms are encouraged to download Form AVN-550 from the TxDOT website as addressed previously. Utilization of Form AVN-550 from a previous download may not be the exact same format. Form AVN-550 is an MS Word Template.

Please note:

Seven completed, unfolded copies of Form AVN-550 **must be received** by TxDOT, Aviation Division at 150 East Riverside Drive, 5th Floor, South Tower, Austin, Texas 78704 no later than July 9, 2007, 4:00 p.m. Electronic facsimiles or forms sent by e-mail will not be accepted. Please mark the envelope of the forms to the attention of Edie Stimach.

The consultant selection committee will be composed of local government members. The final selection by the committee will generally be made following the completion of review of proposals. The committee will review all proposals and rate and rank each. The criteria for evaluating engineering proposals can be found at:

http://www.dot.state.tx.us/services/aviation/consultant.htm

All firms will be notified and the top rated firm will be contacted to begin fee negotiations. The selection committee does, however, reserve the right to conduct interviews for the top rated firms if the committee deems it necessary. If interviews are conducted, selection will be made following interviews.

If there are any procedural questions, please contact Edie Stimach, Grant Manager, or Megan Caffall, Project Manager, for technical questions at 1-800-68-PILOT (74568).

TRD-200702121
Bob Jackson
General Counsel
Texas Department of Transportation
Filed: May 31, 2007

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Request for Proposal for Aviation Engineering Services

The Town of Addison, through its agent the Texas Department of Transportation (TxDOT), intends to engage an aviation professional engineering firm for services pursuant to Government Code, Chapter 2254, Subchapter A. TxDOT Aviation Division will solicit and receive proposals for professional aviation engineering design services described below:

Airport Sponsor: Town of Addison, Addison Airport. TxDOT CSJ No.:0618ADDSN. Scope: Provide engineering/design services to rehabilitate the access road and apron serving the fuel farm.

The DBE goal is set at 10%. TxDOT Project Manager is Alan Schmidt, P.E.

Future scope of work within the next five years may include: upgrade signage, implement declared distances, extend Medium intensity runway lights, upgrade and install precision approach path indicators, airport lighting improvements, overlay, reconstruct, and rehabilitate airside pavements, install Engineered Arresting Materials System, recapture threshold, drainage study, drainage improvements, mitigate obstructions, runway safety area improvements, and pavement marking.

To assist in your proposal preparation the 5010 drawing is available online at **www.dot.state.tx.us/avn/avninfo/notice/consult/index.htm** by selecting "Addison Airport." The proposal should address a technical approach for the current scope only. Firms shall use page 4, Recent Airport Experience, to list relevant past projects for both current and future scope.

Interested firms shall utilize the latest version of Form AVN-550, titled "Aviation Engineering Services Proposal." The form may be requested from TxDOT Aviation Division, 125 East 11th Street, Austin, Texas 78701-2483, phone number, 1-800-68-PILOT (74568). The form may be emailed by request or downloaded from the TxDOT web site at **http://www.dot.state.tx.us/services/aviation/consultant.htm**. The form may not be altered in any way. All printing must be in black on white paper, except for the optional illustration page. Firms must carefully follow the instructions provided on each page of the form. Proposals may not exceed the number of pages in the proposal format. The proposal format consists of seven pages of data plus two optional pages consisting of an illustration page and a proposal summary page. Proposals shall be stapled but not bound in any other fashion. PROPOSALS WILL NOT BE ACCEPTED IN ANY OTHER FORMAT. ATTENTION: To ensure utilization of the latest version of Form AVN-550, firms are encouraged to download Form AVN-550 from the TxDOT website as addressed above. Utilization of Form AVN-550 from a previous download may not be the exact same format. Form AVN-550 is an MS Word Template.

Please note:

Seven completed, unfolded copies of Form AVN-550 **must be received** by TxDOT Aviation Division at 150 East Riverside Drive, 5th Floor, South Tower, Austin, Texas 78704 no later than July 11, 2007, 4:00 p.m. Electronic facsimiles or forms sent by email will not be accepted. Please mark the envelope of the forms to the attention of Amy Slaughter.

The consultant selection committee will be composed of local government members. The final selection by the committee will generally be made following the completion of review of proposals. The committee will review all proposals and rate and rank each. The criteria for evaluating engineering proposals can be found at **http://www.dot.state.tx.us/services/aviation/consultant.htm**. All firms will be notified and the top rated firm will be contacted to begin fee negotiations. The selection committee does, however, reserve the right to conduct interviews of the top rated firms if the committee deems it necessary. If interviews are conducted, selection will be made following interviews.

If there are any procedural questions, please contact Amy Slaughter, Grant Manager, or Alan Schmidt, Project Manager for technical questions at 1-800-68-PILOT (74568).

TRD-200702267
Bob Jackson
General Counsel
Texas Department of Transportation
Filed: June 6, 2007

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University of North Texas System

Notice of Request for Information for Outside Legal Services Related to Real Estate, Oil and Gas, and Mineral Interest Matters

The University of North Texas System (UNT System) requests information from law firms interested in representing the agency and its component institutions in real estate, oil and gas, and mineral interest matters. This Request for Information (RFI) is issued to establish (for the time frame beginning September 1, 2007 to August 31, 2008, with the potential for an extension at the option of the UNT System until August 31, 2009) a referral list from which the UNT System, by and through its Office of Vice Chancellor and General Counsel, will select appropriate counsel for representation on specific real estate, oil and gas, and/or mineral interest matters as the need arises.

Description: The UNT System is comprised of one health institution, the University of North Texas Health Science Center at Fort Worth, and two academic institutions, the University of North Texas and the University of North Texas System Center at Dallas, which are located in three different cities in Texas. Subject to approval by the Office of the Attorney General (OAG) for the State of Texas, the UNT System will engage outside counsel to provide advice and counsel in regard to a broad range of real estate matters involving the Agency and the Agency's component institutions, which shall include but not be limited to addressing issues related to transactions involving real estate, oil and gas, and mineral interests. Counsel will evaluate proposals, review surveys, examine title and title commitments, assist in curing title exceptions and/or defects, draft, review and negotiate contracts and lease agreements, and provide such other guidance and expertise as may be necessary to protect and develop the Agency's varied real estate interests, oil and gas interests, and/or mineral interests in certain properties. Counsel may further be called upon to assist in the acquisition of real estate property and/or mineral interests in certain properties. The UNT System invites responses to this RFI from qualified firms for the provision of such legal services under the direction and supervision of UNT System's Office of Vice Chancellor and General Counsel.

Responses; Qualifications: Responses to this RFI should include at least the following information: (1) a description of the firm's or attorney's qualifications for performing the legal services requested, including the firm's prior experience in real estate, oil and gas and mineral interest-related matters, and appropriate information regarding efforts

made by the firm to encourage and develop the participation of minorities and women in the provision both of the firm's legal services generally and real estate, oil and gas, and mineral interest matters in particular; (2) the names and experience of the attorneys who may be assigned to work on such matters; (3) the submission of fee information (either in the form of hourly rates for each attorney and paralegal who may be assigned to perform services in relation to real estate, oil and gas and mineral interest matters, flat fees, or other fee arrangements directly related to the achievement of specific goals and cost controls) and billable expenses; (4) disclosures of conflicts of interest (identifying each and every matter in which the firm has, within the past calendar year, represented any entity or individual with an interest adverse to the UNT System, a component institution of the UNT System, or to the State of Texas, or any of its boards, agencies, commissions, universities, or elected or appointed officials); and (5) confirmation of willingness to comply with policies, directives and guidelines of the UNT System, the component institutions of the UNT System and the OAG for the State of Texas.

The law firm(s) or attorney(s) will be selected based on demonstrated knowledge and experience, quality of staff assigned to perform services under the contract, compatibility with the goals and objectives of the UNT System, and reasonableness of proposed fees. The successful firm(s) or attorney(s) will be required to sign the Texas OAG's Outside Counsel Agreement, and execution of a contract with the UNT System is subject to approval by the Texas OAG. The UNT System reserves the right to accept or reject any or all responses submitted. The UNT System is not responsible for and will not reimburse any costs incurred in developing and submitting a response.

Format and Person to Contact: Two copies of the response are requested. The response should be typed, preferably double spaced, on 8 1/2 x 11 inch paper with all pages sequentially numbered, and either stapled or bound together. They should be sent by mail, facsimile, or electronic mail, or delivered in person, marked "Response to Request for Information," and addressed to Michelle Williams, Associate General Counsel, University of North Texas System, P.O. Box 310907, Denton, Texas 76203-0907; or e-mail mwilliams@unt.edu or fax to (940) 369-7026.

Deadline for Submission of Response: All responses must be received at the address set forth above no later than 5:00 p.m., July 15, 2007. Questions regarding this request may be directed to Michelle Williams at (940) 565-2717.

TRD-200702261

Joey Saxon

Director of Purchasing and Payment Services

University of North Texas System

Filed: June 5, 2007

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Request for Information - Bond Counsel

PURPOSE

The University of North Texas System (the "System") is requesting information from law firms desiring to serve in a nonexclusive capacity as Bond Counsel for the System.

DESCRIPTION OF SYSTEM AND BOND ISSUANCE AUTHORITY

The University of North Texas System is comprised of the University of North Texas, the University of North Texas Health Science Center at Fort Worth and the University of North Texas System Center at Dallas. The System is governed by a nine-member Board of Regents. The current Board members are: John Robert "Bobby" Ray, Chairman; Burle Pettit; Gayle Strange; Marjorie Craft; Charles Mitchell; Robert Nickell; Al Silva; C. Dan Smith and Rice Tilley, Jr.

Bonds are issued under authority granted the System in Article VII, §17 of the Texas Constitution. Federal tax related matters regarding bonds issued by the System, including strategies and management practices in the conduct of a debt program, requires a close working relationship with Bond Counsel. The System invites responses to this RFI from qualified firms for the provision of such legal services.

TIME SCHEDULE AND PERSON TO CONTACT

Three (3) copies of your response must be submitted by 3:00 p.m. on July 15, 2007 to:

Mr. Phillip Diebel

Vice Chancellor for Finance

University of North Texas System

P.O. Box 310500

Denton, Texas 76203

A duly authorized representative of the firm must execute the submitted response. An unsigned response will not be accepted. Clearly mark the envelopes containing the responses with the following phrase in the lower left hand corner: "IN RESPONSE TO RFI: BOND COUNSEL." All responses become the property of the System. Responses must set forth accurate and complete information as required by this RFI. Oral instructions or offers will not be considered.

It will not be necessary for a representative of your firm to be in attendance at 3:00 p.m. on July 15, 2007.

Responses will be reviewed by the System Administration. After review, certain persons who have responded to the RFI may be requested to elaborate on their responses. After identification of the most highly qualified respondent on the basis of demonstrated competence and qualifications, the System will attempt to negotiate a contract with that respondent at a fair and reasonable price. If a contract cannot be negotiated, the System shall enter into negotiations with the next most highly qualified respondent and this process will continue until a final selection is made or the RFI process is ended.

All respondents to this "Request for Information" will be notified of the System's decision.

Information may be obtained by calling Phil Diebel at 940-565-2055.

RESPONSES

Responses to this RFI should include the following information:

1. A brief description of the firm or attorney's history and general experience.

2. A description of the firm or attorney's qualifications for performing the legal services of Bond Counsel, including prior experience in bond issuance matters and securities law issues for state agencies with particular emphasis on Texas college and university issues.

3. A description of the insurance coverage carried by your law firm, including but not limited to, disclosure of the insurer and policy (ies) limits.

4. The identity of each of the lawyers who will be assigned to work with the University and a description of his or her experience and legal background in rendering legal opinions in the area of public finance.

5. Outline of the firm's general experience during the past five years with the major rating agencies.

6. The submission of fee information (either in the form of hourly rates for each attorney who may be assigned to perform services for the System, flat fees, formula for percentage payment based on bond or financial paper issuance, or other fee arrangements directly related to the achievement of specific goals and cost controls) and billable expenses. In the initial review, this information will only be considered for informational purposes and to establish the current market range with respect to fee information. After a respondent has been identified as the most highly qualified, the System will attempt to negotiate a contract with the respondent that includes a fair and reasonable payment for services.

7. Discuss the management philosophy of the firm as it relates to the control of fees and expenses and allowances for non-billable time. Explain your billing procedure.

8. Provide any other information about the firm that you feel is relevant to the consideration of your firm being chosen as Bond Counsel.

9. Confirmation of willingness to comply with policies, directives and guidelines of the System and the Attorney General of the State of Texas as well as state and federal law.

BASIS OF AWARD

Issuance of this RFI in no way constitutes a commitment by the System to award a contract.

The System will make the selection for Bond Counsel based upon its perception of demonstrated competence and qualifications, including familiarity with public finance and state and federal tax law. The System will also make its selection based on the negotiation of a contract that includes fair and reasonable payment for services.

System Administration will give first consideration to firms whose principal place of business is located in Texas. By issuing this RFI, the System has not committed itself to employ a Bond Counsel. The System also retains the right to employ one or more firms to act as Bond Counsel or to address financial or security issues during the time period in which a contract related to this RFI is in effect. The System reserves the right to make those decisions after receipt of responses and the System Administration's decision on these matters is final.

The System reserves the right to negotiate individual elements of a response and to reject any and all responses. Any award will be contingent on the negotiation of a contract and final approval by the Office of the Attorney General.

SCOPE OF SERVICES AND PAYMENT TERMS

The selected Bond Counsel shall provide representation to the System on specific bond and commercial paper matters, securities law issues, and related financial matters as the need arises. The System's needs include the usual and necessary services of a Bond Counsel in connection with the issuance, sale and delivery of bonds. Bond Counsel shall be responsible for all duties and services necessary or advisable to facilitate the issuance of bonds as stated on the attached schedule. Bond Counsel may also be requested to address issues related to the issuance of commercial paper and increasing the System's self liquidity.

Legal fees and expenses, if any, for legal services under the terms of this engagement that are related to bond or commercial paper issuance shall be paid only out of the principal amount of the issuance and are therefore contingent upon the issuance of the bonds or commercial paper.

Hourly fees shall be paid for work related to increasing the System's self liquidity and for other projects that do not involve issuances and that do involve more than casual or intermittent services. For casual or intermittent services not related to a specific or future bond or commercial issue, no fee will be charged.

There shall not be individual liability of any member of the Board of Regents or other officials of the University, for the payment of any amounts due hereunder.

TERM OF AGREEMENT

The contract term for this engagement will be for the period from September 1, 2007 to August 31, 2008 with a potential extension at the option of the System until August 31, 2009. The System retains the right to terminate the contract for legal services for any reason subject to written notice and upon payment of earned fees and expenses accrued as of the date of termination.

COST INCURRED IN RESPONDING

Issuance of this RFI in no way constitutes a commitment by the System to pay any legal services incurred either in the preparation of a response to this RFI or for the production of any contract for legal services. All costs directly or indirectly related to preparation of a response to this RFI or any supplemental information required to clarify the RFI which may be required by the System shall be the sole responsibility of, and shall be borne by, the Respondent.

RELEASE OF INFORMATION

The System Administration, during the response evaluation process or prior to contract award, shall not release information submitted relative to this request.

OPEN RECORDS

All responses shall be deemed, once submitted, to be the property of the System and subject to the Public Information Act, Chapter 552 of the Texas Government Code.

SCHEDULE OF BOND COUNSEL FEES

The Bond Counsel will perform all usual and necessary legal services as Bond Counsel. Specifically, they will prepare and direct legal proceedings and perform other necessary legal services with reference to the authorization, sale and deliver of bonds, including the following:

1. Preparation of all resolutions and other instruments pursuant to which bonds will be authorized, sold, and delivered in consultation with the Board of Regents of the System; the Underwriters with respect to the bonds, if any; the Financial Advisor; and the officers of the System.

2. Preparation of any trust indenture or trust agreements authorizing or securing the bonds.

3. Attendance at meetings of the Board of Regents of the System to the extent required or requested with reference to the authorization and issuance of the bonds.

4. Attendance at meetings with prospective bond purchasers or rating agencies to the extent required or requested.

5. Attendance at meetings of the State Bond Review Board to the extent required or requested.

6. Obtaining the approval of the bonds of the Attorney General of the State of Texas and the registration of the bonds by the Comptroller of Public Accounts of the State of Texas, as required by law.

7. Supervising the execution of the bonds and delivery thereof to the purchasers.

8. When so delivered, rendering an opinion covering the validity of the bonds under Texas law and the tax-exempt status of the interest thereon under federal income tax laws.

9. Interpretations concerning bond covenants when requested by representatives of the System.

For each separate installment or series of bonds, except "advance refunding bonds," fees covering legal services as Bond Counsel will be calculated as follows:

1. Minimum fee of $_____ for issues the principal amount of which is $10,000,000 or less;

2. For issues the principal amount of which is more than $10,000,000 but not exceeding $25,000,000, $_____ per $1,000 increment of the principle amount;

3. For issues the principal amount of which is more than $25,000,000 but not exceeding $50,000,000, $_____ per $1,000 increment of the principal amount;

4. For issues the principle amount of which is more than $50,000,000 but not exceeding $100,000,000, $_____ per $1,000 increment of the principal amount; and

5. For issues the principle amount of which is more than $100,000,000, $_____ per $1,000 increment of the principle amount.

The fee for "advance refunding" bonds will be $_____ per $1,000 principal amount.

The payment of fees described above shall be contingent upon the delivery of the bonds.

Bond Counsel shall be required to bill in accordance with the UNT System's Outside Counsel Billing Guidelines. Actual out-of-pocket expenses shall be eligible for reimbursement to the extent allowable under the Billing Guidelines.

The above fees do not include any special services not normally included in the legal services performed by Bond Counsel described above, such as (i) litigation; (ii) legal services involving direct responsibility for proceedings before administrative agencies including, by way of example, the Texas Higher Education Coordinating Board; the Internal Revenue Service; the Securities and Exchange Commission; and the State Securities Administrator; (iii) preparation of any prospectuses, official statements, or other materials which must be prepared in accordance with various securities laws; (iv) title examinations or title opinions; and (v) negotiating any special or unusual contracts not necessary for the issuance of bonds.

The University of North Texas System

Office of General Counsel

Outside Counsel Billing Guidelines

These guidelines are intended to give structure and predictability to the relationship between the University of North Texas System and Outside Counsel. From the University of North Texas System's perspective, teamwork is the key to quality and cost-effective legal representation. The University of North Texas System and its component institutions (collectively, UNT System) expect to be billed in accordance with the following Outside Counsel Billing Guidelines:

1) Hourly Rates. The hourly rates for each partner, of counsel, associate and paralegal working on UNT System matters shall be billed at the rates set forth in Addendum B of the Outside Counsel Contract, but shall in no event exceed $500.00 an hour.

2) Billable Time. a) The UNT System will only pay for the services of attorneys, paralegals, patent agents, and technical specialists. All time must be billed in no more than quarter hour increments, and must reflect only actual time spent. Block billing will not be reimbursed. Time entries must note the date performed, identify the legal professional performing the task, describe the task(s) completed, show the time taken to complete each task, and state the applicable hourly rate. Tasks referencing correspondence and filings must describe the document received or authored. The UNT System expects to be billed for the actual time it takes to modify standardized forms, filings, and/or correspondence for use on the matter you are billing. We will not reimburse you for the time it originally took you to prepare them. The UNT System will not pay for review, execution, and processing of the standard Outside Counsel Contract. No formula or value billing is permitted.

b) The UNT System will not pay for attorneys or paralegals of the firm educating themselves, training, or doing work of a transient nature on a UNT System matter. Each designated professional is expected to perform work of a type commensurate with his/her professional title. Without prior approval, the UNT System will not pay for more than one attorney or legal professional to perform any task. The UNT System will also not pay for duplicate review and/or analysis of documents or legal research. The UNT System's view is that the most efficient use of attorney time is to maintain continuous contact with the file so that it is not necessary to review the file to reacquaint themselves. Thus, repeated time spent reviewing the file should not be necessary and will not be reimbursed.

c) Legal research must be pre-approved by the UNT System. A request to undertake legal research should provide the UNT System with an estimate of either time or dollar amount to be expended. The need for legal research will be addressed on a case-by-case basis.

d) All conferences must describe the attendees and purpose of the meeting, and, if more than one firm member is in attendance, a justification for multiple attendees from the firm.

e) The UNT System will not pay for Administrative Staff, such as secretarial support, case clerks, and accounting and billing clerks, including but not limited to the following: overtime, file opening, file organization, docketing or other administrative tasks; preparation of billing, invoice review, budget preparation or communications regarding same or any other accounting matter.

3) Expenses. The UNT System expects you to anticipate and include expenses and disbursements as part of your overhead and, therefore, part of your basic hourly rate. Accordingly, the UNT System will not reimburse the firm for:

a) Expenses disallowed under the terms and conditions set forth in the Outside Counsel Contract;

b) Copying charges (routine, day-to-day);

c) Fax charges;

d) Routine postage;

e) Office supplies;

f) Local, long distance or cellular telephone charges;

g) Local travel within the Dallas-Fort Worth-Denton Metroplex, including mileage, parking and tolls; and

h) All delivery services incurred by in-firm staff.

The UNT System will reimburse the actual cost for the following expenses:

i) Pre-approved volume copying;

j) Overnight courier charges and third party courier services, with an explanation of the nature and purpose of the charge (i.e., why the task was not completed in a timely manner to permit reduced rates); and

k) Allowable expenses as expressly stated in Provision 5.2.2 of the Outside Counsel Contract.

All other expenses must be included within the hourly rates of the firm unless they are truly extraordinary and the UNT System advance approval has been obtained prior to incurring the expense.

4) Invoices. The UNT System expects a firm's invoices to show the same high quality and care it takes with its legal work. Professional time and disbursements should be reviewed by the billing partner and those portions that are not necessary for the legal task(s) described should be deleted before the bill is submitted for payment.

a) Invoices for legal services shall be submitted to the person designated in the Outside Counsel Contract, preferably in electronic form via email, within 10 business days of the end of the month in which legal services are rendered.

b) Each statement should indicate the UNT System institution for which the legal services were performed and the Outside Counsel Contract number under which the legal services were performed.

c) Allowable costs and expenses should be billed in accordance with the guidelines set forth in paragraph 3 above and supported by attached copies of invoices for amounts in excess of $50.00.

d) A summary sheet should be included indicating the total legal fees and expenses, the amount of the contract and the total legal fees and expenses invoiced to date.

It is the responsibility of the firm to monitor the total amount of fees and expenses invoiced under the contract. Once 75% of the contract amount has been invoiced and the remaining 25% will not cover the estimated legal fees and expenses for the remaining term of the contract, the firm should advise the UNT System Office of General Counsel (OGC) in writing requesting an increase in the contract amount and stating the reason for the additional legal fees and expenses. An amendment will be prepared for signature by the firm, UNT System and the Attorney General. Legal services rendered exceeding the contract amount are not allowed and will not be paid. It is the firm's responsibility to advise the Office of General Counsel prior to exceeding the contract limit.

If you have questions regarding these guidelines or any outside counsel matters, please contact:

Michelle Williams

Associate General Counsel

The University of North Texas System

P.O. Box 310907

Denton, TX 76203-0907

(940) 565-2717

mwilliams@unt.edu

TRD-200702266
Joey Saxon
Director of Purchasing and Payment Services
University of North Texas System
Filed: June 6, 2007

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How to Use the Texas Register

Information Available: The 14 sections of the ***Texas Register*** represent various facets of state government. Documents contained within them include:

Governor - Appointments, executive orders, and proclamations.

Attorney General - summaries of requests for opinions, opinions, and open records decisions.

Secretary of State - opinions based on the election laws.

Texas Ethics Commission - summaries of requests for opinions and opinions.

Emergency Rules- sections adopted by state agencies on an emergency basis.

Proposed Rules - sections proposed for adoption.

Withdrawn Rules - sections withdrawn by state agencies from consideration for adoption, or automatically withdrawn by the Texas Register six months after the proposal publication date.

Adopted Rules - sections adopted following public comment period.

Texas Department of Insurance Exempt Filings - notices of actions taken by the Texas Department of Insurance pursuant to Chapter 5, Subchapter L of the Insurance Code.

Texas Department of Banking - opinions and exempt rules filed by the Texas Department of Banking.

Tables and Graphics - graphic material from the proposed, emergency and adopted sections.

Transferred Rules- notice that the Legislature has transferred rules within the *Texas Administrative Code* from one state agency to another, or directed the Secretary of State to remove the rules of an abolished agency.

In Addition - miscellaneous information required to be published by statute or provided as a public service.

Review of Agency Rules - notices of state agency rules review.

Specific explanation on the contents of each section can be found on the beginning page of the section. The division also publishes cumulative quarterly and annual indexes to aid in researching material published.

How to Cite: Material published in the ***Texas Register*** is referenced by citing the volume in which the document appears, the words "TexReg" and the beginning page number on which that document was published. For example, a document published on page 2402 of Volume 30 (2005) is cited as follows: 30 TexReg 2402.

In order that readers may cite material more easily, page numbers are now written as citations. Example: on page 2 in the lower-left hand corner of the page, would be written "30 TexReg 2 issue date," while on the opposite page, page 3, in the lower right-hand corner, would be written "issue date 30 TexReg 3."

How to Research: The public is invited to research rules and information of interest between 8 a.m. and 5 p.m. weekdays at the ***Texas Register*** office, Room 245, James Earl Rudder Building, 1019 Brazos, Austin. Material can be found using ***Texas Register*** indexes, the ***Texas Administrative Code***, section numbers, or TRD number.

Both the ***Texas Register*** and the ***Texas Administrative Code*** are available online through the Internet. The address is: http://www.sos.state.tx.us. The ***Register*** is available in an .html version as well as a .pdf (portable document format) version through the Internet. For website subscription information, call the Texas Register at (800) 226-7199.

Texas Administrative Code

The ***Texas Administrative Code (TAC***) is the compilation of all final state agency rules published in the ***Texas Register***. Following its effective date, a rule is entered into the ***Texas Administrative Code***. Emergency rules, which may be adopted by an agency on an interim basis, are not codified within the ***TAC***.

The ***TAC*** volumes are arranged into Titles and Parts (using Arabic numerals). The Titles are broad subject categories into which the agencies are grouped as a matter of convenience. Each Part represents an individual state agency.

The complete TAC is available through the Secretary of State's website at http://www.sos.state.tx.us/tac. The following companies also provide complete copies of the TAC: Lexis-Nexis (1-800-356-6548), and West Publishing Company (1-800-328-9352).

The Titles of the ***TAC***, and their respective Title numbers are:

1. Administration
4. Agriculture
7. Banking and Securities
10. Community Development
13. Cultural Resources
16. Economic Regulation
19. Education
22. Examining Boards
25. Health Services
28. Insurance
30. Environmental Quality
31. Natural Resources and Conservation
34. Public Finance
37. Public Safety and Corrections
40. Social Services and Assistance
43. Transportation

How to Cite: Under the ***TAC*** scheme, each section is designated by a ***TAC*** number. For example in the citation 1 TAC §27.15: 1 indicates the title under which the agency appears in the ***Texas Administrative Code***; ***TAC*** stands for the ***Texas Administrative Code***; §27.15 is the section number of the rule (27 indicates that the section is under Chapter 27 of Title 1; 15 represents the individual section within the chapter).

How to update: To find out if a rule has changed since the publication of the current supplement to the ***Texas Administrative Code***, please look at the ***Table of TAC Titles Affected***. The table is published cumulatively in the blue-cover quarterly indexes to the ***Texas Register*** (January 21, April 15, July 8, and October 7, 2005). If a rule has changed during the time period covered by the table, the rule's ***TAC*** number will be printed with one or more ***Texas Register*** page numbers, as shown in the following example.

TITLE 40. SOCIAL SERVICES AND ASSISTANCE
Part I. Texas Department of Human Services
40 TAC §3.704.....950, 1820

The ***Table of TAC Titles Affected*** is cumulative for each volume of the ***Texas Register*** (calendar year).