TEXAS REGISTER

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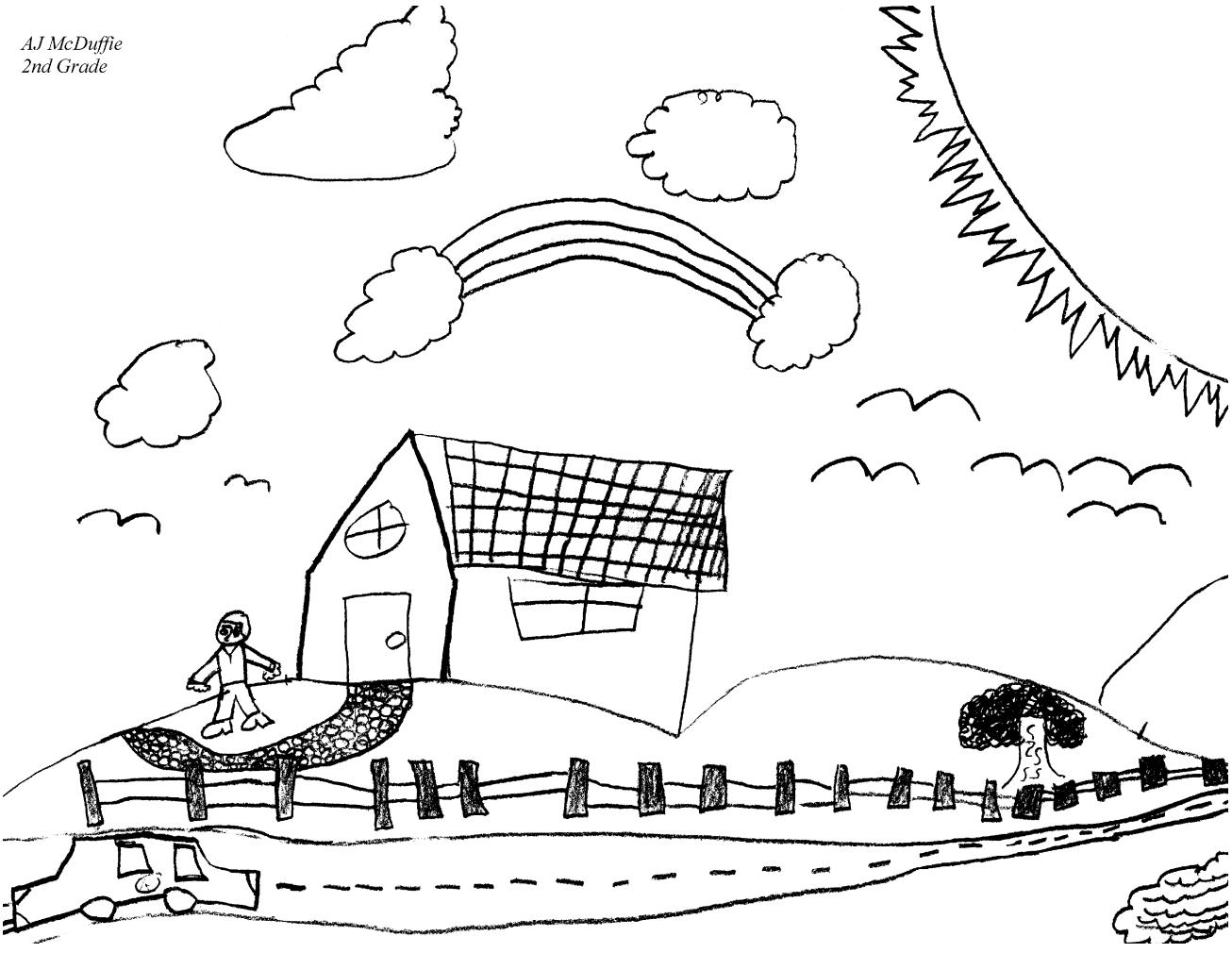
AJ McDuffie
2nd Grade



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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IN THIS ISSUE

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.

THE ATTORNEY GENERAL

The *Texas Register* publishes summaries of the following: Requests for Opinions, Opinions, Open Records Decisions.

An index to the full text of these documents is available from the Attorney General's Internet site http://www.oag.state.tx.us. Telephone: 512-936-1730. For information about pending requests for opinions, telephone 512-463-2110.

An Attorney General Opinion is a written interpretation of existing law. The Attorney General writes opinions as part of his responsibility to act as legal counsel for the State of Texas. Opinions are written only at the request of certain state officials. The Texas Government Code indicates to whom the Attorney General may provide a legal opinion. He may not write legal opinions for private individuals or for any officials other than those specified by statute. (Listing of authorized requestors: http://www.oag.state.tx.us/opinopen/opinhome.shtml.)

Request for Opinions

RQ-0615-GA

Requestor:

The Honorable Keri Roberts

Mills County Attorney

Post Office Box 160

Goldthwaite, Texas 76844

Re: Whether a county may fund a water district (RQ-0615-GA)

Briefs requested by October 1, 2007

RQ-0616-GA

Requestor:

The Honorable Kim Brimer

Chair, Committee on Administration

Texas State Senate

Post Office Box 12068

Austin, Texas 78711

Re Whether "document fees" constitute part of an automotive shop's worker's lien (Request No. 0616-GA)

Briefs requested by October 1, 2007

RQ-0617-GA

Requestor:

The Honorable Richard L. "Rick" Hardcastle

Chair, Committee on Energy Resources

Texas House of Representatives

P.O. Box 2910

Austin, Texas 78768-2910

Re: Whether a state agency must use an average of 100 Mcf per day of natural gas in order to qualify for the exemption provided by section 104.202 of the Utilities Code (RQ-0617-GA)

Briefs requested by October 4, 2007

For further information, please access the Web site at www.oag.state.tx.us or call the Opinion Committee at (512) 463-2110.

TRD-200704075
Stacey Napier
Deputy Attorney General
Office of the Attorney General
Filed: September 4, 2007

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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 10. DEPARTMENT OF INFORMATION RESOURCES

CHAPTER 201. PLANNING AND MANAGEMENT OF INFORMATION RESOURCES TECHNOLOGIES

1 TAC §201.19

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

The Department of Information Resources (department or DIR) proposes the repeal of 1 TAC §201.19, concerning establishment of quality assurance guidelines for projects in Texas state agencies. Section 201.19, which established DIR model quality assurance guidelines for agencies to develop internal quality assurance procedures, will be superseded by proposed new project management practices rules at 1 TAC Chapter 216, published separately.

Dustin Lanier, Director of Policy, Planning and Measurement for the department, has determined that there will be no fiscal implications for state and local governments as a result of repealing the rule.

Mr. Lanier has also determined that for each year of the first five years the proposed repeal is in effect the public will benefit from the repeal, because the rule is being replaced with new project management practices rules. There are no anticipated economic costs to individuals or small businesses.

Comments on the proposed repeal of 1 TAC §201.19 may be submitted to Renée Mauzy, General Counsel, Department of Information Resources, 300 West 15th Street, Suite 1300, Austin, Texas 78701, *renee.mauzy@dir.state.tx.us* for 30 days following publication of this repeal.

The repeal is proposed pursuant to §2054.052(a), Texas Government Code, which authorizes the department to adopt rules necessary to implement its responsibilities under the Information Management Resources Act, and pursuant to §2054.153, Texas Government Code, which requires the department to adopt rules that establish guidelines for project management practices.

No other statutes are affected by repeal of this rule.

§201.19. Establishment of Quality Assurance Guidelines for Projects in Texas State Agencies.

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 August 31, 2007.

TRD-200704058
Renée Mauzy
General Counsel
Department of Information Resources
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-4700

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CHAPTER 216. PROJECT MANAGEMENT PRACTICES

The Department of Information Resources (department) proposes new 1 TAC Chapter 216, Subchapter A, §§216.1 - 216.3; Subchapter B §§216.10 - 216.12; and Subchapter C §§216.20 - 216.22, concerning project management practices applicable to state agencies and institutions of higher education. The rules are promulgated to implement Section 6 of House Bill 1789, 80th Legislative Session, which amended §§2054.151 - 2054.157, Texas Government Code, relating to project management practices. Section 2054.153, Texas Government Code, requires the department to adopt rules that establish guidelines for project management practices. The proposed rules are further authorized by §2054.052(a), Texas Government Code, which authorizes the department to adopt rules necessary to implement its responsibilities under the Information Resources Management Act. In a separate rulemaking, the department will propose the repeal of 1 TAC §201.19, concerning quality assurance guidelines.

Section 216.1 sets forth applicable terms and technologies for project management practices. Section 216.2 defines state agencies, other than institutions of higher education. Section 216.3 defines institutions of higher education.

Section 216.10 requires each agency to have a policy that communicates an agency-wide approach for project management practices. Section 216.11 requires each agency to manage information resources projects based on project management practices that meet certain criteria. Section 216.12 requires each agency to identify and adopt one or more standards to meet project management requirements in certain knowledge areas.

Section 216.20 requires each institution of higher education to have a policy that communicates an institution-wide approach for project management practices. Section 216.21 requires each institution of higher education to manage information resources projects based on project management practices that meet cer-

tain criteria. Section 216.22 requires each institution of higher education to identify and adopt one or more standards to meet project management requirements in certain knowledge areas.

Because the proposed rules apply to institutions of higher education, the department, in consultation with the Information Technology Council for Higher Education, prepared an analysis of the impact of the rules that included consideration of the requirements in §2054.121(c), Texas Government Code. Issues and concerns regarding the potential impact of the rules on higher education, student populations and federal grant requirements were identified, including: (1) the proposed rules require approval by the agency head. Institutions of higher education require such policies be approved by someone other than the head of the institution; (2) the term "integration" should be clarified; and (3) certain definitions should be revised. The department proposed alternatives to address the issues, which were acceptable to the Information Technology Council for Higher Education, including: (1) authorizing the approval of the project management practices by the institution of higher education's president, chancellor or designee; (2) eliminating use of the term "integration"; and (3) explaining that certain definitions were statutorily required and could be addressed legislatively in the future.

Dustin Lanier, Director of Policy, Planning and Measurement for the department, has determined that for the first five-year period the proposed rules are in effect there will be varying fiscal implications for state government as a result of enforcing or administering the proposed rules. Agencies and institutions of higher education with existing project management practices that satisfy requirements will have no fiscal impact. Agencies and institutions of higher education that choose to use project management practices from another agency or institution of higher education will have minimal fiscal impact. Such impact may vary based on the adjustments to the policy the agency or institution of higher education makes. Agencies that choose to fully develop project management practices may have considerable fiscal impact depending on the approach, staffing requirements and agency needs.

Mr. Lanier has also determined that for each year of the first five years the proposed rules are in effect the public benefits anticipated as a result of enforcing or administering the rules will be more effective use of public and financial resources and improved delivery of technology projects among affected governmental entities. There are no anticipated economic costs to persons or small businesses required to comply with the proposed rules.

Comments on the proposed rules may be submitted to Renée Mauzy, General Counsel, Department of Information Resources, 300 West 15th Street, 13th Floor, Austin, Texas 78701, *renee.mauzy@dir.state.tx.us* for 30 days following publication.

SUBCHAPTER A. DEFINITIONS

1 TAC §§216.1 - 216.3

The new rules are proposed under §2054.153(a), Texas Government Code, which requires the department to adopt rules that establish guidelines for project management practices and §2054.052(a), Texas Government Code, which authorizes the department to adopt rules necessary to implement its responsibilities under the Information Resources Management Act.

No other statutes are affected by these rules.

§216.1. Applicable Terms and Technologies for Project Management Practices.

The following words and terms, when used with this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Agency head--Top-most senior manager with operational accountability for an agency, such as an executive director, commissioner, university president, university chancellor, comptroller, or board president.

(2) Component--Elements of project management practices such as project management methodologies, tools, techniques, and methods for integration with other similar or related disciplines that influence information resources project delivery.

(3) Department--Department of Information Resources.

(4) Information resources--Procedures, equipment, and software that are employed, designed, built, operated, and maintained to collect, record, process, store, retrieve, display, and transmit information, and associated personnel including consultants and contractors.

(5) Information resources technologies--Data processing and telecommunications hardware, software, services, supplies, personnel, facility resources, maintenance, and training.

(6) Process--Series of steps and strategies used to achieve specific goals and results.

(7) Methodology--Set of inter-related processes, tasks, activities, or principles that can be scaled and applied to a specific situation; provides a list of activities, indicates how to accomplish the activities, and identifies who executes the activities and when.

(8) Project--A program to provide information resources technologies support to functions within or among elements of a state agency, which should be characterized by well-defined parameters, specific objectives, common benefits, planned activities, a scheduled completion date, and an established budget with a specified source of funding.

(9) Project management practices--Documented and repeatable methods that a state agency uses to apply knowledge, skills, tools, and techniques to satisfy project activity requirements.

(10) Standard--A definition, format, or specification that has been approved by a recognized, formal, national and international standards organization or is accepted as a de facto standard by the industry.

§216.2. State Agency.

A department, commission, board, office, council, authority, or other agency, other than an institution of higher education, in the executive or judicial branch of state government that is created by the constitution or a statute of this state.

§216.3. Institution of Higher Education.

A university system or institution of higher education as defined by §61.003, Education Code.

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 August 31, 2007.

TRD-200704059
Renée Mauzy
General Counsel
Department of Information Resources
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-4700

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SUBCHAPTER B. PROJECT MANAGEMENT PRACTICES FOR STATE AGENCIES

1 TAC §§216.10 - 216.12

The new rules are proposed under §2054.153(a), Texas Government Code, which requires the department to adopt rules that establish guidelines for project management practices and §2054.052(a), Texas Government Code, which authorizes the department to adopt rules necessary to implement its responsibilities under the Information Resources Management Act.

No other statutes are affected by these rules.

§216.10. Policy.

Each state agency shall institute, approve, and publish an operating procedure that communicates an agency-wide approach for project management practices. At a minimum, the operating procedure will:

(1) Identify components and general use of project management practices, citing sources of reusable components adopted from another agency or institution of higher education that satisfy requirements specified under §216.11 of this subchapter; and

(2) Be approved by the agency head or designee.

§216.11. Requirements.

Each state agency shall manage information resources projects based on project management practices that meet the following criteria:

(1) Include a method for delivery of information resources projects that solve business problems;

(2) Include a method for governing application of project management practices;

(3) Be documented, repeatable, and include a single reference source (e.g., handbook, guide, repository) that communicates how to effectively apply use of the project management practices components;

(4) Include a project classification method developed by DIR (see http://www.dir.state.tx.us/projectdelivery/projectmgmt/classify/index.htm), the agency, or another source that:

(A) Distinguishes and categorizes projects according to level of complexity and risk (e.g., technology, size, budget, time to deliver); and

(B) Defines how to use the project classification method to establish, scale, and execute the appropriate level of processes;

(5) Include a method to periodically review, assess, monitor, and measure the impact of project management practices on the agency's ability to achieve its core mission;

(6) Align with use of the Texas Project Delivery Framework;

(7) Accommodate use of other practices and methods that intersect with application of project management practices; and

(8) Be reviewed and updated at least annually to help ensure continuous process improvement.

§216.12. Standards.

Each state agency shall identify and adopt one or more standards as a basis for project management practices to meet project requirements in a minimum of the following knowledge areas:

(1) integration management;

(2) scope management;

(3) schedule management;

(4) cost management;

(5) quality management;

(6) resources management;

(7) communications management;

(8) risk management; and

(9) procurement (acquisition) management.

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-200704060
Renée Mauzy
General Counsel
Department of Information Resources
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-4700

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SUBCHAPTER C. PROJECT MANAGEMENT PRACTICES FOR INSTITUTIONS OF HIGHER EDUCATION

1 TAC §§216.20 - 216.22

The new rules are proposed under §2054.153(a), Texas Government Code, which requires the department to adopt rules that establish guidelines for project management practices and §2054.052(a), Texas Government Code, which authorizes the department to adopt rules necessary to implement its responsibilities under the Information Resources Management Act.

No other statutes are affected by these rules.

§216.20. Policy.

Each institution of higher education shall institute, approve, and publish an operating procedure that communicates an institution-wide approach for project management practices. At a minimum, the operating procedure will:

(1) Identify components and general use of project management practices, citing sources of reusable components adopted from a state agency or another institution of higher education that satisfy requirements specified under §216.21 of this subchapter; and

(2) Be approved by the president or chancellor of the institution of higher education or designee.

§216.21. Requirements.

Each institution of higher education shall manage information resources projects based on project management practices that meet the following criteria:

(1) Include a method for delivery of information resources projects that solve business problems;

(2) Include a method for governing application of project management practices;

(3) Be documented, repeatable, and include a single reference source (e.g., handbook, guide, repository) that communicates how

to effectively apply use of the project management practices components;

(4) Include a project classification method developed by DIR (see http://www.dir.state.tx.us/projectdelivery/projectmgmt/classify/index.htm), the institution of higher education, or another source that:

(A) Distinguishes and categorizes projects according to level of complexity and risk (e.g., technology, size, budget, time to deliver); and

(B) Defines how to use the project classification method to establish, scale, and execute the appropriate level of processes;

(5) Include a method to periodically review, assess, monitor, and measure the impact of project management practices on the institution of higher education's ability to achieve its core mission;

(6) Align with use of the Texas Project Delivery Framework;

(7) Accommodate use of other practices and methods that intersect with application of project management practices; and

(8) Be reviewed and updated at least annually to help ensure continuous process improvement.

§216.22. Standards.

Each institution of higher education shall identify and adopt one or more standards as a basis for project management practices to meet project requirements in a minimum of the following knowledge areas:

(1) integration management;

(2) scope management;

(3) schedule management;

(4) cost management;

(5) quality management;

(6) resources management;

(7) communications management;

(8) risk management; and

(9) procurement (acquisition) management.

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 August 31, 2007.

TRD-200704061
Renée Mauzy
General Counsel
Department of Information Resources
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-4700

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PART 15. TEXAS HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 358. MEDICAID ELIGIBILITY SUBCHAPTER E. INCOME

1 TAC §358.450

Pursuant to House Bill 52, 80th Legislature, Regular Session, 2007, which amends §32.024(w) of the Human Resources Code, the Texas Health and Human Services Commission (HHSC) proposes to amend §358.450(h), relating to General Principles Concerning Income. The purpose of this amendment is to clarify that HHSC is the entity responsible for setting the personal needs allowance for Medicaid recipients who are residents of long-term care facilities and shall set it in accordance with §32.024(w), Human Resources Code.

Background and Justification

House Bill 52, amending §32.024(w), Human Resources Code, increased the minimum amount that can be set for the personal needs allowance from $45 to $60. The personal needs allowance, established under federal law, is the amount of income an individual in a long-term care facility may retain to purchase goods and services. The proposed amendment to §358.450(h) deletes the current minimum amount of $45 and permits HHSC's Executive Commissioner to set the personal needs allowance at an amount consistent with §32.024(w), Human Resources Code, without the need for future amendments to the rule should the statutory minimum change. The statutory increase of the minimum amount for the personal needs allowance aligns the statute with current practice.

The proposed amendment also deletes language in subsection (h), which is no longer applicable, indicating that the effective date of subsection (h) had been September 1, 2003.

Analysis of §358.450

The proposed amendment provides that HHSC's Executive Commissioner shall set the personal needs allowance in accordance with §32.024 of the Human Resources Code. The proposed amendment also replaces a reference to the Department of Human Services Commissioner with a reference to the Health and Human Services Executive Commissioner as the official who sets the amount of the personal needs allowance. The proposed amendment deletes the reference to $45 as the minimum amount for the personal needs allowance.

Fiscal Note

Thomas M. Suehs, Deputy Executive Commissioner for Financial Services, has determined that during the first five-year period the proposed amendment is in effect, there will be no fiscal implications for state government. The personal needs allowance is currently set at $60. No policy changes are required. No automation changes are required. The proposed rule change will not result in any fiscal implications for local health and human services agencies. Local governments will not incur additional costs.

Small and Micro-business Impact Analysis

Mr. Suehs has also determined that there will be no effect on small or micro businesses as a result of enforcing or administering the proposed amendment, as they will not be required to alter their business practices. There are no anticipated economic costs to persons who are required to comply with the proposed amendment. There is no anticipated negative impact on local employment.

Public Benefit

Anne Heiligenstein, Deputy Executive Commissioner for Social Services, has determined that for each of the first five years the proposed amendment is in effect, the public will benefit from the adoption of the amended rule. The anticipated public benefit of

the proposed amendment is that the personal needs allowance amount for Medicaid residents in long-term care facilities will not be less than $60 a month.

Regulatory Analysis

HHSC has determined that this proposal is not a "major environmental rule" as defined by §2001.0225 of the Texas Government Code. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risks to human health from environmental exposure and that may adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

Takings Impact Assessment

HHSC has determined that this proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under §2007.043 of the Government Code.

Public Comment

Written comments on the proposal may be submitted to Dee Church at Mail Code 2090, P.O. Box 12668, Austin, Texas 78711-2668, by fax to (512) 206-5211, or by e-mail to dee.church@hhsc.state.tx.us within 30 days of publication of the proposal in the *Texas Register*.

Statutory Authority

This amendment is proposed 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.

The proposed new rule affects the Human Resources Code, Chapter 32, and the Texas Government Code, Chapter 531. No other statutes, articles, or codes are affected by this proposal.

§358.450. General Principles Concerning Income.

(a) - (g) (No change.)

(h) A personal needs allowance (PNA) is an amount of a client's income that a client in an institutional setting may retain for his personal use. It will not be applied against the costs of medical assistance furnished in the facility. Each client [~~Clients~~] in an institutional setting [~~settings and each spouse in couple cases~~] may retain a PNA in an amount set by the executive commissioner of the Health and Human Services Commission in accordance with Chapter 32 of the Texas Human Resources Code. [~~of no less than $45. This amount will be set by the commissioner of DHS.~~] For SSI clients who receive the $30 reduced federal benefit, the [~~commissioner will set a~~] state will issue a supplement to allow for a PNA at the minimum level set by the executive commissioner [~~of $45 for personal needs. The effective date of this section is September 1, 2003~~].

(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 August 31, 2007.

TRD-200704047

Steve Aragón
Chief Counsel
Texas Health and Human Services Commission
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 424-6900

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TITLE 16. ECONOMIC REGULATION

PART 4. TEXAS DEPARTMENT OF LICENSING AND REGULATION

CHAPTER 73. ELECTRICIANS

16 TAC §§73.10, 73.20 - 73.22, 73.24, 73.25, 73.40, 73.51, 73.52, 73.54, 73.80, 73.90

The Texas Department of Licensing and Regulation ("Department") proposes amendments to existing rules at 16 Texas Administrative Code, §§73.10, 73.20, 73.21, 73.22, 73.24, 73.25, 73.40, 73.51, 73.52, 73.80, and 73.90; and new rule §73.54 regarding the electricians program.

These rules are necessary to implement the provisions of Senate Bill 1222 adopted by the 80th Legislature providing for licensure of residential appliance installers and residential appliance installation contractors. The rules are clarified in that the supervisory responsibilities of contractors are more clearly defined and requirements for maintenance of records are set out. Provisions of the rules that were adopted to implement grandfathering provisions of the original statute are deleted as they no longer apply.

Section 73.10(6) is amended to add electrical sign contractors to the definition of general supervision. Section 73.10(7) is amended to add a requirement that the on-site supervising licensee must be on the job site when electrical work is being performed. Section 73.10(17) is amended by deleting language referring to replacement of raceways, conductors, disconnecting means or service feeder components thereby broadening the scope of work a maintenance electrician may perform. Section 73.10(18) is amended by adding language to make it clear that sign electricians may work on pole lighting in parking lots. Section 73.10(19) is amended to add the phrase, "or authorized representatives" to the list of persons who may perform electrical work on an electrical equipment manufacturer's products without being licensed. This amendment will bring the rule into compliance with the provisions of Senate Bill 1222. New §73.10(23) is added to describe the scope of work for residential appliance installers. New §73.10(24) is added to describe the scope of work for a residential appliance installation contractor. New §73.10(25) is added to clarify ambiguities in the statutory definition of residential appliance. The new sections are added to bring the rules into compliance with the provisions of Senate Bill 1222.

Section 73.20(a)(1) is amended to add residential appliance installers to the list of individual applicants who must pass an examination. Section 73.20(e) is amended to add references to statutory §§1305.1615, 1305.1617 and 1305.1618.

Section 73.21(b)(1) is deleted since it sets a deadline for applying for licensure of electricians by grandfathering that has already passed. New §73.21(b)(2) has been added to set out the requirements for licensure as an appliance installer without passing an examination as provided in Section 8 of Senate Bill 1222.

Section 73.22(d) is amended to add residential appliance installation contractors to the prohibition against contractors using a license number that is not assigned to them.

Section 73.24(a) is amended to add sign electricians and appliance installers to the list of individual licensees that are eligible for licensure by reciprocity if they are licensed in a state with which Texas has a reciprocity agreement. Section 73.24(b) is amended to slightly alter the focus of the section. As amended, it provides that the examination is waived if the Executive Director determines that an applicant has demonstrated that he meets the requirements of §73.21(b) rather than providing that the Executive Director may waive the examination if he determines that the provisions of §73.21 have been met. Section 73.24(c) is amended to more clearly set out what is required of applicants in subsections (c)(1) and (c)(2). Subsection (c)(3) is deleted as it related to proof required to obtain licensure by a grandfathering provision that no longer applies. Subsections (d) and (e) are deleted for the same reason that subsection (c)(3) is deleted.

Section 73.25(d) is amended by deleting the phrase, "for one renewal". Subsections (h) and (i) are deleted since they relate to timing provisions that are no longer effective.

Section 73.40(a) is amended to add a reference to residential appliance installation contractors to require that they have the same insurance coverage that electrical and electrical sign contractors must have.

Section 73.51(b) is amended to change a contractor's responsibility for electrical work it performs to responsibility for work performed on the contractor's behalf. New §73.51(d) is added to require a contractor to maintain its employment records and records of work performed on its behalf and to make them available to the Department. New §73.51(e) is added to state that both a contractor and the contractor's designated master are responsible for the supervision of all licensees working on the contractor's behalf.

Section 73.52(b) is amended to change a sign contractor's responsibility for electrical sign work it performs to responsibility for work performed on the contractor's behalf. New §73.52(d) is added to require a contractor to maintain its employment records and records of work performed on its behalf and to make them available to the Department. New §73.52(e) is added to state that both a contractor and the contractor's designated master are responsible for the supervision of all licensees working on the contractor's behalf.

New §73.54 is added to set out responsibilities of residential appliance installation contractors in the same fashion that §73.51 and §73.52 set out responsibilities of electrical contractors and electrical sign contractors. The structure of all three rule sections is similar.

Section 73.80 is amended by adding paragraphs (11) and (12) to establish application and renewal fees for appliance installers, $40.00, and appliance installation contractors, $125.00.

Section 73.90 is amended to delete language that refers to rules currently found in 16 Texas Administrative Code, Chapter 60.

William H. Kuntz, Jr., Executive Director, has determined that for the first five-year period the proposed amendments and new rules are in effect there will be no cost to state or local government as a result of enforcing or administering the amendments or new rules

Mr. Kuntz also has determined that for each year of the first five-year period the amendments and new rules are in effect, the public benefit will be that the provisions of Senate Bill 1222, 80th Legislature given effect in the rules and the rules will more clearly define contractor requirements.

There will be some economic costs imposed on persons and businesses that must be licensed under these rules that implement the provisions of Senate Bill 1222, 80th Legislature. Also, residential appliance installation contractors will have to purchase insurance to comply with these rules.

Comments on the proposal may be submitted to Caroline Jackson, Legal Assistant, General Counsel's Office, Texas Department of Licensing and Regulation, P.O. Box 12157, Austin, Texas 78711, or facsimile (512) 475-3032, or electronically: erule.comments@license.state.tx.us. The deadline for comments is 30 days after publication in the *Texas Register*.

The amendments and new rules are proposed under Texas Occupations Code, Chapter 1305 and Chapter 51, which authorizes the Department to adopt rules as necessary to implement this chapter and any other law establishing a program regulated by the Department.

The statutory provisions affected by the proposal are those set forth in Texas Occupations Code, Chapter 1305 and Chapter 51. No other statutes, articles, or codes are affected by the proposal.

§73.10. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise.

(1) Assumed name--A name used by a business as defined in the Business and Commerce Code, Title 4, Chapter 36, Subchapter A, §36.02.

(2) Business affiliation--The business organization to which a master licensee may assign his or her license.

(3) Employee--An individual who performs tasks assigned to him by his employer. The employee is subject to the deduction of social security and federal income taxes from his pay. An employee may be full time, part time, or seasonal.

(4) Employer--One who employs the services of employees, pays their wages, deducts the required social security and federal income taxes from the employee's pay, and directs and controls the employee's performance.

(5) Filed--A document is deemed to have been filed with the department on the date that the document has been received by the department or, if the document has been mailed to the department, the date a postmark is applied to the document by the U.S. Postal Service.

(6) General Supervision--Exercise of oversight by a master electrician on behalf of an electrical contractor, or electrical sign contractor, or by a master sign electrician on behalf of an electrical sign contractor of performance by all classes of electrical licensees of electrical work bearing responsibility for the work's compliance with applicable codes under Texas Occupations Code, Chapter 1305.

(7) On-Site Supervision--Exercise of supervision of electrical work or electrical sign work by a licensed individual other than an electrical apprentice. Continuous supervision of an electrical apprentice is not required, though the on-site supervising licensee is responsible for review and inspection of the electrical apprentice's work to ensure compliance with any applicable codes or standards.

(8) Electrical Contractor--A person, or entity, licensed as an electrical contractor, that is in the business of performing "Electrical Contracting" as defined by Texas Occupations Code, §1305.002(5).

(9) Master Electrician--An individual, licensed as a master electrician, who on behalf of an electrical contractor, electrical sign contractor, or employing governmental entity, performs "Electrical Work" as defined by Texas Occupations Code, §1305.002(11).

(10) Journeyman Electrician--An individual, licensed as a journeyman electrician, who works under the general supervision of a master electrician, on behalf of an electrical contractor, or employing governmental entity, while performing "Electrical Work" as defined by Texas Occupations Code, §1305.002(11).

(11) Electrical Apprentice--An individual, licensed as an apprentice who works under the on-site supervision of a master electrician, a journeyman electrician, or a residential wireman, on behalf of an electrical contractor, or employing governmental entity performing "Electrical Work" as defined by Texas Occupations Code, §1305.002(11).

(12) Electrical Sign Contractor--A person, or entity, licensed as an electrical sign contractor, that is in the business of performing "Electrical Sign Contracting" as defined by Texas Occupations Code, §1305.002(9).

(13) Master Sign Electrician--An individual, licensed as a master sign electrician, who, on behalf of an electrical sign contractor, performs "Electrical Sign Work" as defined in paragraph (18) of this section.

(14) Journeyman Sign Electrician--An individual, licensed as a journeyman sign electrician, who works under the general supervision of a master electrician or a master sign electrician, on behalf of an electrical sign contractor, while performing "Electrical Sign Work" as defined in paragraph (18) of this section.

(15) Residential Wireman--An individual, licensed as a residential wireman, who works under the general supervision of a master electrician, on behalf of an electrical contractor, or employing governmental entity, while performing electrical work that is limited to electrical installations in single family and multifamily dwellings not exceeding four stories, as defined by Texas Occupations Code, §1305.002(13).

(16) Maintenance Electrician--An individual, licensed as a maintenance electrician, who works under the general supervision of a master electrician, on behalf of an electrical contractor, or employing governmental entity and performs "Electrical Maintenance Work" as defined in paragraph (17) of this section.

(17) Electrical Maintenance Work--The replacement, or repair of existing electrical appurtenances, apparatus, equipment, machinery, or controls used in connection with the use of electrical energy in, on, outside, or attached to a building, residence, structure, property, or premises. All replacements or repairs must be of the same rating and type as the existing installation. No improvements may be made that are necessary to comply with applicable codes under Texas Occupations Code, Chapter 1305. Electrical maintenance work does not include [~~the replacement of any raceways, conductors, disconnecting means, or service feeder components. It also does not include~~] the installation of any new electrical appurtenances, apparatus, equipment, machinery, or controls beyond the scope of any existing electrical installation.

(18) Electrical Sign Work--Any labor or material used in manufacturing, installing, maintaining, extending, connecting or reconnecting an electrical wiring system and its appurtenances, apparatus or equipment used in connection with signs, outline lighting, awnings, signals, light emitting diodes, and the repair of existing outdoor electric discharge lighting, including parking lot pole lighting. This also includes the installation of an electrical service integral to an isolated sign and/or outline lighting installation

(19) Work Involved in the Manufacture of Electrical Equipment--Work involved in the manufacture of electrical equipment includes on and off-site manufacture, commissioning, testing, calibration, coordination, troubleshooting, evaluation, repair or retrofits with components of the same ampacity, maintenance and servicing of electrical equipment within their enclosures performed by authorized employees, or authorized representatives of electrical equipment manufacturers and limited to the type of products they manufacture.

(20) Electrical Sign Apprentice--An individual, licensed as an electrical sign apprentice who works under the on-site supervision of a master electrician, a master sign electrician, or a journeyman sign electrician, on behalf of an electrical sign contractor performing "Electrical Sign Work" as defined by these rules.

(21) A Principal Place of Business--For purposes of these rules, a contractor has a principal place of business in another state or territory or foreign country if the contractor is doing business in Texas without complying with all applicable Texas statutes and the contractor conducts substantial business in another state, territory or country while business conducted by the contractor in Texas is minimal.

(22) On-the-job Training--Training or experience performing electrical work as defined by Occupations Code §1305.002(11).

(23) Residential Appliance Installer--An individual, licensed as a residential appliance installer, who on behalf of a residential appliance installation contractor, performs electrical work that is limited to residential appliance installation as defined by Texas Occupations Code, §1305.002(12-e).

(24) Residential Appliance Installation Contractor--A person or entity licensed as a residential appliance installation contractor, that is in the business of residential appliance installation as defined by Texas Occupations Code §1305.002(12-d).

(25) Residential Appliance--A unit of electrical equipment that is designed and installed in a dwelling by direct connection to an existing electrical circuit to perform a specific function such as water heating, for example. The term does not include general use equipment, such as an electric motor, for example, that is not designed for a specific function, nor does it include luminaries or suspended paddle fans.

§73.20. Licensing Requirements--Applicant and Experience Requirements.

(a) An applicant for a license must submit the required fees with a completed application and the appropriate attachments:

(1) Applicants for Master Electrician, Master Sign Electrician, Journeyman Electrician, Journeyman Sign Electrician, Residential Wireman, [~~and~~] Maintenance Electrician, and Residential Appliance Installer licenses must submit proof of a passing grade on the accepted examination.

(2) Applicants for contractor's licenses must submit proof of general liability insurance and either workers' compensation insurance or a certificate of authority to self insure, or a statement that the applicant has elected not to obtain workers' compensation insurance pursuant to Subchapter A, Chapter 406, Labor Code, with the initial and renewal applications.

(b) An applicant must complete all requirements within one year of the date the application is filed.

(c) Except as provided by §73.24, each individual applicant must pass all parts of a Department accepted examination, and provide proof of a passing grade, before the applicant will be licensed. To be accepted, an examination must have been taken and passed no more than two years before the date of the application.

(d) For purposes of this chapter, 2,000 hours of on the job training shall equal one year of on the job training. On the job training must be established by letter(s) setting out dates of employment from persons who either employed or supervised the applicant or as required by the application. Letters must include the name and license type of the supervising person.

(e) Each applicant must meet the applicable eligibility requirements as set forth in the Occupations Code, §§1305.153-1305.1618 [~~§§1305.153-1305.161~~].

(f) Obtaining a license by fraud or false representation is grounds for denial, suspension, or revocation of a license and/or an administrative penalty.

§73.21. Licensing Requirements--Examinations.

(a) To obtain by examination a license issued under this chapter, an individual applicant must successfully complete an examination approved by the Executive Director of the Texas Department of Licensing and Regulation.

(b) To obtain a license without examination, an applicant must either;

[~~(1) file a completed application and the provisions of Section 12, House Bill 1317 of the 79th Legislative Session and §73.24 must be met on or before December 31, 2005; or,~~]

(1) [~~(2)~~] have been licensed for the preceding year by a municipality or regional licensing authority that has terminated its licensing program and have applied for a state issued license within ninety days of the date the program stopped issuing or renewing licenses; or

(2) be an applicant for licensure as a residential appliance installer, and

(A) have completed 4,000 hours of electrical work, or appliance installation work under the supervision of a master electrician; and

(B) apply for licensure no later than June 1, 2008.

§73.22. Licensing Requirements--General.

(a) A license issued under this chapter is valid for one year from the date of issuance and must be renewed annually.

(b) A person shall not perform work requiring a license under Title 8, Occupations Code, Chapter 1305 with an expired license.

(c) Falsification of information on an application or cheating on an examination is grounds for denial, suspension, or revocation of a license and/or an administrative penalty.

(d) An electrical contractor, [~~or~~] an electrical sign contractor, or a residential appliance installation contractor shall not use a license number that is not assigned to that contractor by the Department.

(e) A license is not transferable.

(f) Altering a license in any way is prohibited and is grounds for a sanction and/or penalty.

(g) If a licensee contracts with a general contractor or a home warranty company to provide installation or service that requires a license under the Act, the licensee remains responsible for the integrity of that work.

(h) A person using the license of another person or allowing another person to use his license shall be subject to license denial, suspension, or revocation and/or assessment of an administrative penalty.

§73.24. Licensing Requirements--Waiver of Examination Requirements.

(a) An applicant who is licensed in another state that has entered into a reciprocity agreement with Texas regarding licensure of electricians, sign electricians, or residential appliance installers may obtain an equivalent license in Texas without passing the examination, provided that all other licensure requirements are met.

(b) The [~~Executive Director may waive the~~] examination requirement is waived if, based upon acceptable proof, the Executive Director determines that the provisions of §73.21(b) [~~§73.21~~] are met.

(c) Acceptable proof of an applicant's qualifications must be presented on a form prescribed by the Department that [~~may include any or all of the following~~]:

(1) [~~a form prescribed by the Department that~~] certifies completion of the required hours of on-the-job training under the supervision of a master electrician or master sign electrician as appropriate, or [~~.~~]

(2) is [~~a form prescribed by the Department and~~] completed by the municipality or region in which the applicant was licensed for at least one year.

[~~(3) a transcript, diploma or certificate evidencing graduation from an applicable apprenticeship program with the required number of hours of job-related education. The apprenticeship program must be approved and registered by the U.S. Department of Labor, Bureau of Apprenticeship and Training or other organizations recognized by the Department~~]

[~~(d) An applicant applying for licensure in an area in which a municipal or regional licensing program exists and who works in the area, without passing an examination, may obtain a state issued license that is equivalent to the municipal or regional license held at the time of application.~~]

[~~(e) An applicant who lives and works in an area where no municipal or regional licensing program exists, without passing an examination, may obtain a state issued master electrician's license or a master sign electrician's license if the applicant has 20,000 hours of on-the-job electrical experience acquired while working in an area where no municipal or regional licensing program existed while under the supervision of a master electrician recognized by the department.~~]

§73.25. Continuing Education.

(a) Terms used in this section have the meanings assigned by Chapter 59 of this title, unless the context indicates otherwise.

(b) To renew a license listed in Texas Occupations Code, §1305.168(a), an individual licensee must complete four hours of continuing education in courses approved by the department.

(c) The continuing education hours must have been completed within the term of the current license, in the case of a timely renewal. For a late renewal, the continuing education hours must have been completed within one year prior to the date of renewal.

(d) A licensee may not receive continuing education credit for attending the same course more than once [~~for one renewal~~].

(e) For each annual renewal, an individual licensee must complete a course, or combination of courses, dedicated to instruction in:

(1) the National Electrical Code, as adopted under Title 8, Occupations Code §1305.101, or the current version of the National

Electrical Code, as approved by the National Fire Protection Association; and

(2) state law and rules that regulate the conduct of licensees.

(f) A licensee shall retain a copy of the certificate of completion for a course for one year after the date of completion. In conducting any inspection or investigation of the licensee, the department may examine the licensee's records to determine compliance with this subsection.

(g) To be approved under Chapter 59 of this title, a provider's course must be dedicated to instruction in:

(1) the National Electrical Code, as adopted under Title 8, Occupations Code §1305.101, or the current version of the National Electrical Code, as approved by the National Fire Protection Association; and/or

(2) state law and rules that regulate the conduct of licensees.

~~[(h) If a provider files a course approval application prior to January 1, 2005 and the department subsequently approves the course, a provider may submit to the department a completion report for hours of instruction completed from March 1, 2004 to the course approval date. The completion report must be submitted on the appropriate department-approved form. Continuing education credit will be awarded to a participant under this subsection if the provider submits sufficient documentation to satisfy the department that the hours of instruction offered prior to the course approval date were substantially similar to the course subsequently approved by the department.]~~

~~[(i) Section 59.51(d) of this title does not apply to hours of instruction or courses completed prior to the course approval date under subsection (h) of this section.]~~

§73.40. Insurance Requirements.

(a) Electrical contractors, ~~[and]~~ electrical sign contractors, and residential appliance installation contractors are required to maintain at least the minimum general liability insurance coverages at all times to satisfy proof of financial responsibility.

(1) The insurance must: be at least $300,000 per occurrence (combined for property damage and bodily injury);

(2) be at least $600,000 aggregate (total amount the policy will pay for property damage and bodily injury coverage); and

(3) be at least $300,000 aggregate for products and completed operations.

(b) A license applicant or licensee shall file with the Department a completed certificate of insurance or other evidence satisfactory to the Department when applying for initial and renewal licenses and upon request of the Department.

(c) Proof of the required general liability and workers' compensation insurance can be submitted on an industry standard certificate of insurance form with a 30 day cancellation notice. Workers' compensation coverage may be established by a certificate of authority to self insure, or an applicant may state that it has elected not to obtain workers' compensation coverage.

(d) A licensed contractor shall furnish the name of the insurance carrier, policy number, name, address, and telephone number of the insurance agent with whom the contracting company is insured to any customer who requests it.

(e) Insurance must be obtained from an admitted company or an eligible surplus lines carrier, as defined in the Texas Insurance Code, Chapter 981, or other insurance companies that are rated by A.M. Best Company as B+ or higher.

§73.51. Electrical Contractors' Responsibilities.

(a) A licensed electrical contractor shall display its name and license number on both sides of each vehicle owned or operated by the business and used in the conduct of electrical work. Lettering shall be of a contrasting color and at least two inches in height. The license number shall be preceded by the letters "TECL".

(b) All of a contractor's non-exempt electrical work shall be performed by licensed individuals. A contractor is responsible for compliance with applicable codes for all such electrical work performed on its behalf [~~it performs~~].

(c) The electrical contractor's name, address, phone number, and license number shall appear on all proposals, invoices, and written contracts proposed by the contractor. The following information: "Regulated by The Texas Department of Licensing and Regulation, P.O. Box 12157, Austin, Texas 78711, 1-800-803-9202, 512-463-6599; website: www.license.state.tx.us/complaints" shall be listed on invoices and written contracts.

(d) A licensed electrical contractor shall maintain employee records and records of all work performed on its behalf for a period of four years after completion of the work, and shall make those records available to the Department at the contractor's place of business during normal business hours for inspection and copying.

(e) A licensed electrical contractor and its designated master electrician are responsible for supervision of all licensees performing work on behalf of the contractor to assure compliance with applicable statutes and rules and in particular, standards of conduct set out in these rules.

§73.52. Electrical Sign Contractors' Responsibilities.

(a) A licensed electrical sign contractor shall display its name and license number on both sides of each vehicle owned or operated by the business and used in the conduct of electrical sign work. Lettering shall be of a contrasting color and at least two inches in height. The license number shall be preceded by the letters "TSCL".

(b) All of a contractor's non-exempt electrical sign work shall be performed by licensed individuals. A contractor is responsible for compliance with applicable codes for all such electrical sign work performed on its behalf [~~it performs~~].

(c) The electrical sign contractor's name, address, phone number, and license number shall appear on all proposals, invoices, and written contracts proposed by the contractor. The following information: "Regulated by The Texas Department of Licensing and Regulation, P.O. Box 12157, Austin, Texas 78711, 1-800-803-9202, 512-463-6599; website: www.license.state.tx.us/complaints" shall be listed on invoices and written contracts.

(d) A licensed electrical sign contractor shall maintain employee records and records of all work performed on its behalf for a period of four years after completion of the work, and shall make those records available to the Department at the contractor's place of business during normal business hours for inspection and copying.

(e) A licensed electrical sign contractor and its designated master electrician or master sign electrician are responsible for supervision of all licensees performing work on behalf of the contractor to assure compliance with applicable statutes and rules and in particular, standards of conduct set out in these rules.

§73.54. Residential Appliance Installation Contractors' Responsibilities.

(a) A licensed residential appliance installation contractor shall display its name and license number on both sides of each vehicle owned or operated by the business and used in the conduct of residential appliance installation work. Lettering shall be of a contrasting color and at least two inches in height. The license number shall be preceded by the letters "TICL".

(b) All of a contractor's non-exempt residential appliance installation work shall be performed by licensed individuals. A contractor is responsible for compliance with applicable codes for all such residential appliance installation work performed on its behalf.

(c) The residential appliance installation contractor's name, address, phone number, and license number shall appear on all proposals, invoices, and written contracts proposed by the contractor. The following information: "Regulated by The Texas Department of Licensing and Regulation, P.O. Box 12157, Austin, Texas 78711, 1-800-803-9202, 512-463-6599; website: www.license.state.tx.us/complaints" shall be listed on invoices and written contracts.

(d) A licensed residential appliance installation contractor shall maintain employee records and records of all work performed on its behalf for a period of four years after completion of the work, and shall make those records available to the Department at the contractor's place of business during normal business hours for inspection and copying.

(e) A licensed residential appliance installation contractor and its designated appliance installer are responsible for supervision of all licensees performing work on behalf of the contractor to assure compliance with applicable statutes and rules and in particular, standards of conduct set out in these rules.

§73.80. Fees.

(a) Application and renewal fees:

(1) Master Electrician--$65

(2) Master Sign Electrician--$65

(3) Journeyman Electrician--$40

(4) Journeyman Sign Electrician--$40

(5) Residential Wireman--$25

(6) Maintenance Electrician--$25

(7) Electrical Contractor--$125

(8) Electrical Sign Contractor--$125

(9) Electrical Apprentice--$20

(10) Electrical Sign Apprentice--$20

(11) Residential Appliance Installer--$40

(12) Residential Appliance Installation Contractor--$125

(b) Late Renewal Fees. Late renewal fees for licenses issued under this chapter are provided under §60.83 of this title (relating to Late Renewal Fees).

(c) Revised or duplicate license fees:

(1) All licenses except as set out below--$25

(2) Electrical Apprentice--$20

(3) Electrical Sign Apprentice--$20

(d) All fees are non-refundable.

§73.90. Sanctions--Administrative Sanctions/Penalties.

If a person violates any provision of Title 8, Occupations Code, Chapter 1305, any provision of Title 16, Texas Administrative Code, Chapter 73, or any provision of an order of the Executive Director or Commission, proceedings may be instituted to impose administrative penalties, administrative sanctions, or both administrative penalties and sanctions in accordance with the provisions of Title 8, [~~Texas Civil Statutes, Chapter 1305, Texas~~] Occupations Code, Chapters [~~Chapter~~] 51 and 1305 [~~; and Title 16, Texas Administrative Code, Chapter 60~~].

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 August 31, 2007.

TRD-200704062
William H. Kuntz, Jr.
Executive Director
Texas Department of Licensing and Regulation
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-4765

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TITLE 19. EDUCATION

PART 2. TEXAS EDUCATION AGENCY

CHAPTER 89. ADAPTATIONS FOR SPECIAL POPULATIONS

SUBCHAPTER GG. COMMISSIONER'S RULES CONCERNING DROPOUT PREVENTION STRATEGIES

19 TAC §89.1701

The Texas Education Agency (TEA) proposes new §89.1701, concerning the dropout prevention strategy plan. The proposed new section would implement the requirements of the Texas Education Code (TEC), §29.918, as added by House Bill (HB) 2237, 80th Texas Legislature, 2007, which requires the commissioner by rule to establish procedures through which districts with a high dropout rate will submit a plan detailing the manner in which the compensatory education allotment and the high school allotment will be used as part of a dropout prevention strategy.

HB 2237, 80th Texas Legislature, 2007, added the TEC, §29.918, requiring districts with a high dropout rate to develop a dropout prevention strategy plan. This plan must detail the manner in which a district will use its resources, specifically the compensatory education allotment and the high school allotment, to contribute to the district's dropout prevention strategy. The compensatory education allotment, established through the TEC, §42.152, provides an annual allotment to districts based on the number of economically disadvantaged students enrolled at campuses in the district. The compensatory education allotment is intended to increase the academic achievement and high school completion rates for at-risk students. Similarly, the high school allotment, as detailed in the TEC, §42.2516(b)(3), provides funding to districts to improve graduation and college readiness rates for Texas secondary school students.

In addition to a dropout prevention strategy plan, the Legislature, in previous legislation, mandated that certain districts develop two other plans--a school improvement plan and a plan to

increase college enrollment--both of which may address issues related to a district's dropout rate. Under the TEC, §39.1323, a campus with a specific state accountability rating is required to work with a campus intervention team and to design a school improvement plan addressing factors contributing to the campus' rating as academically unacceptable. In addition, under the TEC, §29.904, a campus with a low college-going rate is required to enter into an agreement with a nearby institution of higher education to develop a plan to increase the percentage of its graduating seniors enrolling in an institution of higher education. The newly mandated requirement for a dropout prevention strategy plan offers an opportunity to coordinate these three plans, where appropriate.

The proposed new 19 TAC §89.1701, Dropout Prevention Strategy Plan, would implement the TEC, §29.918, relative to the dropout prevention strategies. The proposed new rule would establish applicable definitions and specify that affected districts would be identified and notified annually of the requirement to submit a dropout prevention strategy plan. The proposal would also address coordination of a dropout prevention strategy plan with a plan to increase college enrollment and with a school improvement plan. Submission of a plan by a school district and review of a plan by the TEA are also addressed as well as conditions under which the commissioner of education could impose sanctions.

Barbara Knaggs, acting senior advisor for education initiatives, has determined that for the first five-year period the new section is in effect there will be no fiscal implications for state and local government as a result of enforcing or administering the new section.

Ms. Knaggs has determined that for each year of the first five years the new section is in effect the public benefit anticipated as a result of enforcing the new section will be that districts with high dropout rates will create and implement plans that will strategically coordinate resources to enact dropout prevention strategies. Both the public and students will benefit from dropout prevention strategies because more students will graduate ready to enter college and the workforce. There will be no effect on small businesses. There is no anticipated economic cost to persons who are required to comply with the new section.

The public comment period on the proposal begins September 14, 2007, and ends October 14, 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 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 new section is proposed under the Texas Education Code, §29.918, which authorizes the commissioner to adopt rules to administer dropout prevention strategies.

The new section implements the Texas Education Code, §29.918.

§89.1701. Dropout Prevention Strategy Plan.

(a) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Compensatory education allotment--Funds allocated under the Texas Education Code (TEC), §42.152.

(2) Dropout prevention strategy plan--The document prepared for submission to the Texas Education Agency (TEA) in compliance with the TEC, §29.918, and in accordance with specifications set forth in subsection (e) of this section.

(3) High school allotment--Funds allocated under the TEC, §42.2516(b)(3).

(4) Plan to increase college enrollment--The document prepared in compliance with the TEC, §29.904, for submission to the TEA by a district ranked among the lowest 10% of districts, based on its college-going rate. A district's college-going rate is calculated as the percentage of its graduating class enrolled in higher education the fall after completing high school.

(5) School district--For the purposes of this section, the definition of school district includes an open-enrollment charter school.

(6) School improvement plan--The document prepared for submission to the TEA by a school district in compliance with the TEC, §39.1323, or by a school district with a campus rated academically unacceptable for failure to meet the required performance standards set forth in the TEC, §39.073.

(b) Identification of districts with a high dropout rate. In accordance with the TEC, §29.918(a), a school district with a high dropout rate, as defined by the commissioner of education, shall be identified and notified annually of the requirement to submit a dropout prevention strategy plan as specified by this section.

(c) Coordination with statutory requirement to submit a plan to increase college enrollment. If a school district is required by statute to submit both a dropout prevention strategy plan and a plan to increase college enrollment, the school district must describe in its dropout prevention strategy plan how the activities identified in both plans will be coordinated.

(d) Coordination with statutory requirement to submit a school improvement plan.

(1) If a school district is required by statute to submit both a school improvement plan due to failure to meet the required performance standard regarding dropout rates or completion rates as well as a dropout prevention strategy plan, then the school district may request that its school improvement plan be used to satisfy the requirements of both statutes. To exercise this option, a school district superintendent must submit a request in writing to the commissioner of education for approval.

(2) A school improvement plan used to satisfy the statutory requirements of both plans, as provided in paragraph (1) of this subsection, must clearly identify those programs and activities to be funded with compensatory education allotment and high school allotment funds.

(e) Dropout prevention strategy plan specifications.

(1) A school district identified as having a high dropout rate under subsection (b) of this section shall submit a dropout prevention strategy plan to the commissioner describing the manner in which it intends to use its compensatory education allocation and high school allocation funds for the purpose of developing and implementing dropout prevention strategies.

(2) A school district's dropout prevention strategy plan shall include the following components:

(A) analysis of factors that have had an impact on the school district or campus dropout rate using evaluation and needs assessment data available to the school district;

(B) description of programs and activities designed to reduce the school district and campus dropout rate to be funded in whole or in part with compensatory education allotment funds;

(C) description of programs and activities identified in §61.1093 of this title (relating to Use of Funds) designed to reduce the school district and campus dropout rate to be funded in whole or in part with high school allotment funds;

(D) quantifiable benchmarks to measure evidence of change;

(E) resources to be used in implementing programs and activities identified in subparagraphs (B) and (C) of this paragraph;

(F) timeline for initiation of activities identified in subparagraphs (B) and (C) of this paragraph; and

(G) description of how activities will be coordinated with those identified in the school district's plan to increase college enrollment, if the school district is required by the TEC, §29.904, to submit such a plan.

(3) The dropout prevention strategy plan shall include research-based programs and activities.

(f) Dropout prevention strategy plan submission. In accordance with the TEC, §29.918(a), a school district shall submit its dropout prevention strategy plan not later than December 1 of each school year preceding the school year in which the school district will receive the compensatory education allotment or high school allotment. The plan shall be submitted to the TEA in a manner determined by the commissioner.

(g) Dropout prevention strategy plan approval. In accordance with the TEC, §29.918(b), review of district dropout prevention strategy plans shall be completed by the commissioner not later than March 1 of the school year preceding the school year in which the district will receive the compensatory education allotment or high school allotment. Until a district receives commissioner approval in writing for its dropout prevention strategy plan, a district may not spend or obligate more than 25% of the district's compensatory education allotment or high school allotment funds as set forth in the TEC, §29.918(b).

(h) Sanctions. The commissioner may impose sanctions under the TEC, §39.131 or §39.1321, if the district:

(1) fails to submit its dropout prevention strategy plan by December 1;

(2) submits a dropout prevention strategy plan that fails to meet the plan specifications set forth in subsection (e) of this section; or

(3) spends or obligates compensatory education allotment or high school allotment funds in excess of 25% of the allotment amount prior to receiving approval of the dropout prevention strategy plan by the commissioner.

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 August 31, 2007.

TRD-200704056

Cristina De La Fuente-Valadez
Director, Policy Coordination
Texas Education Agency
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-1497

CHAPTER 103. HEALTH AND SAFETY SUBCHAPTER AA. COMMISSIONER'S RULES CONCERNING PHYSICAL FITNESS

19 TAC §103.1001

The Texas Education Agency (TEA) proposes new §103.1001, concerning student physical fitness assessment. The proposed new section would adopt in rule the requirement that school districts and open-enrollment charter schools shall assess student physical fitness. The proposal would implement rule action required by Senate Bill (SB) 530, 80th Texas Legislature, 2007.

Through SB 530, the 80th Texas Legislature added the Texas Education Code (TEC), Chapter 38, Health and Safety, Subchapter C, Physical Fitness Assessment, requiring school districts to annually assess the physical fitness of students enrolled in Grades 3-12. TEC, §38.102, requires the commissioner of education to adopt an assessment instrument to be used by school districts in assessing student physical fitness. The statute also identifies specific factors the instrument must assess and requires criterion-referenced standards specific to a student's age and gender based on the physical fitness level required for good health.

Proposed new 19 TAC Chapter 103, Subchapter AA, §103.1001, would implement the TEC, §38.102, by adopting a rule that specifies that the commissioner of education shall determine the assessment instrument to be used by school districts and open-enrollment charter schools to assess the physical fitness of students. The proposed new rule would also address student exemptions.

Local school districts will be required to collect, maintain, and submit specified physical fitness assessment data. Through a separate rulemaking process, the TEA will propose rules relating to the collection and analysis of aggregated data on the fitness assessment components in compliance with SB 530.

Jeff Kloster, associate commissioner for health, safety, and school readiness, has determined that for the first five-year period the new section is in effect there will be no fiscal implications for state and local government as a result of enforcing or administering the new section.

Mr. Kloster has determined that for each year of the first five years the new section is in effect the public and student benefit anticipated as a result of enforcing the new section will be increasing public awareness of quality physical education programs, emphasizing the importance of community and school-based support of school health programming, and bringing focus on resources and funding for school-based physical activity and health education programs. The proposal would also strengthen physical education and physical activity programs to ensure health improvement among the student population, including a gradual reduction in childhood obesity and Type II diabetes. There will be no effect on small businesses. There is no anticipated economic cost to persons who are required to comply with the new section.

The public comment period on the proposal begins September 14, 2007, and ends October 14, 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 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 new section is proposed under the Texas Education Code, §38.102, which authorizes the commissioner to adopt by rule an assessment instrument to be used by a school district in assessing student physical fitness. Texas Education Code, §38.106, authorizes the commissioner to adopt rules necessary to implement the Texas Education Code, Chapter 38, Subchapter C.

The new section implements the Texas Education Code, §38.102 and §38.106.

§103.1001. Student Physical Fitness Assessment.

(a) In accordance with the Texas Education Code (TEC), Chapter 38, Subchapter C, each school district and open-enrollment charter school shall annually assess the physical fitness of students enrolled in Grades 3-12.

(b) Each student must be assessed based on factors related to student health, including the factors specified in the TEC, §38.102, unless a particular factor is inappropriate for that student because of a health classification as defined in 19 TAC §74.31 of this title (relating to Health Classifications for Physical Education).

(c) The assessment that each school district and open-enrollment charter school shall use to assess student physical fitness will be the assessment instrument selected by the commissioner of education through a request for offers process.

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-200704057
Cristina De La Fuente-Valadez
Director, Policy Coordination
Texas Education Agency
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-1497

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TITLE 22. EXAMINING BOARDS

PART 9. TEXAS MEDICAL BOARD

CHAPTER 162. SUPERVISION OF MEDICAL SCHOOL STUDENTS

22 TAC §162.1

The Texas Medical Board proposes an amendment to §162.1, concerning Supervision of Medical Students.

The amendment updates the name of the Texas Medical Board. Elsewhere in this issue of the *Texas Register,* the Texas Medical Board contemporaneously proposes the rule review of Chapter 162, Supervision of Medical School Students.

Robert D. Simpson, General Counsel, Texas Medical Board, has determined that for the first five-year period the amendment is in effect there will be no fiscal implications to state or local government as a result of enforcing the section as proposed. There will be no effect to individuals required to comply with the rule as proposed.

Mr. Simpson also has determined that for each year of the first five years the amendment as proposed is in effect the public benefit anticipated as a result of enforcing the section will be an updated rule. There will be no effect on small or micro businesses.

Comments on the proposal may be submitted to Sally Durocher, P.O. Box 2018, Austin, Texas 78768-2018. A public hearing will be held at a later date.

The amendment is proposed under the authority of the Texas Occupations Code Annotated, §153.001, which provides authority for the Texas Medical Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

Texas Occupations Code Annotated, §152.001 is affected by the proposal.

§162.1. Supervision of Medical Students.

Only a physician with a current and unrestricted Texas medical license may supervise a medical student if the medical student meets the following criteria:

(1) is enrolled at a Texas medical school;

(2) is a student at a medical school located outside Texas and is enrolled as a visiting student at a Texas medical school; or

(3) will receive supervised medical education in a Texas hospital or teaching institution sponsoring or participating in a program of graduate medical education accredited by the Accrediting Council for Graduate Medical Education, the American Osteopathic Association, or the Texas Medical Board [~~State Board of Medical Examiners~~] in the same subject as the medical or osteopathic medical education in which the hospital or teaching institution has an agreement with the applicant's school.

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 August 31, 2007.

TRD-200704022
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
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For further information, please call: (512) 305-7016

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CHAPTER 173. PHYSICIAN PROFILES

22 TAC §§173.1, 173.2, 173.5

The Texas Medical Board proposes amendments to §§173.1, 173.2, and 173.5, concerning Physician Profiles.

The amendments update the name of the Texas Medical Board, set grounds for disciplinary action to include the omission of required information when providing physician profile information, and establish when the Board will amend a physician's profile.

Elsewhere in this issue of the *Texas Register,* the Texas Medical Board contemporaneously proposes the rule review of Chapter 173, Physician Profiles.

Robert D. Simpson, General Counsel, Texas Medical Board, has determined that for the first five-year period the amendments are in effect there will be no fiscal implications to state or local government as a result of enforcing the sections as proposed. There will be no effect to individuals required to comply with the rules as proposed.

Mr. Simpson also has determined that for each year of the first five years the amendments as proposed are in effect the public benefit anticipated as a result of enforcing the sections will give the public more accurate profile information regarding licensees. There will be no effect on small or micro businesses.

Comments on the proposal may be submitted to Sally Durocher, P.O. Box 2018, Austin, Texas 78768-2018. A public hearing will be held at a later date.

The amendments are proposed under the authority of the Texas Occupations Code Annotated, §153.001 and §154.006, which provide authority for the Texas Medical Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

No other statutes, articles are codes are affected by the proposal.

§173.1. Profile Contents.

(a) The Texas Medical Board [~~State Board of Medical Examiners~~] (the "board") shall develop and make available to the public a comprehensive profile of each licensed physician electronically via the Internet or in paper format upon request.

(b) The profile of each licensed physician shall contain the following information listed in paragraphs (1) - (25) of this subsection:

(1) full name;

(2) place of birth if the physician requests that it be included in the physician's profile;

(3) gender;

(4) ethnic origin if the physician requests that it be included in the physician's profile;

(5) name of each medical school attended and the dates of:

(A) graduation; or

(B) Fifth Pathway designation and completion of the Fifth Pathway Program;

(6) a description of all graduate medical education in the United States or Canada, including:

(A) beginning and ending dates;

(B) program name;

(C) city and state of program;

(D) type of training (internship, residency or fellowship); and

(E) specialty of program;

(7) any specialty certification held by the physician and issued by a board that is a member of the American Board of Medical Specialties or the Bureau of Osteopathic Specialists;

(8) primary and secondary specialties practiced, as designated by the physician;

(9) the number of years the physician has actively practiced medicine in:

(A) the United States or Canada; and

(B) Texas;

(10) the original date of issuance of the physician's Texas medical license;

(11) the expiration date of the physician's registration permit;

(12) the physician's current registration, disciplinary and licensure statuses;

(13) the name and city of each hospital in Texas in which the physician has privileges;

(14) the physician's primary practice location (street address, city, state and zip code);

(15) the type of language translating services, including translating services for a person with impairment of hearing, that the physician provides at the physician's primary practice location;

(16) whether the physician participates in the Medicaid program;

(17) whether the physician's patient service areas are accessible to disabled persons, as defined by federal law;

(18) a description of any conviction for an offense constituting a felony, a Class A or Class B misdemeanor, or a Class C misdemeanor involving moral turpitude;

(19) a description of any charges reported to the board to which the physician has pleaded no contest, for which the physician is the subject of deferred adjudication or pretrial diversion, or in which sufficient facts of guilt were found and the matter was continued by a court of competent jurisdiction;

(20) a description of any public board action against the physician;

(21) a description of any disciplinary action against the physician by a medical licensing board of another state;

(22) a description of the final resolution taken by the board on medical malpractice claims or complaints required to be opened by the board under the Medical Practice Act (the "Act"), Tex. Occ. Code Ann. §164.201;

(23) a description of any formal complaint issued by the board's staff against the physician and initiated and filed with the State Office of Administrative Hearings under §164.005 of the Act and the status of the complaint;

(24) a description of a maximum of five awards, honors, publications or academic appointments submitted by the physician, each no longer than 120 characters; and

(25) a description of any medical malpractice claim against the physician, not including a description of any offers by the physician to settle the claim, for which the physician was found liable, a jury awarded monetary damages to the claimant, and the award has been determined to be final and not subject to further appeal.

§173.2. Profile Update and Correction Form.

(a) The board shall develop a Profile Update and Correction Form (the "Form") which allows for corrections and/or updates to the profile information to be made by the physician. The physician must submit all changes to profile information upon this Form, or indicate on the Form that no changes are necessary. The Form shall contain the date the information will be made available to the public and will allow the physician to request a copy of the physician's profile. Upon such request, and when the profile information has been updated, the board shall provide a copy to the physician. The Form will be made available in hard copy and on the Internet.

(b) Compliance with the request for information from the board is mandatory. Failure to return the completed Form to the board shall be considered non-compliance. Non-compliance shall result in nonrenewal of the physician's license until such time as the physician provides the requested information.

(c) Submission of false or misleading information or omission of required information by the physician shall be considered grounds for disciplinary action.

(d) All data contained in the profile shall indicate the source of the data and the last update date.

§173.5. Updates to the Physician's Profile Due to Information Received by a Third Party.

(a) When the board is notified by a third party of a change in profile information for a physician, the board shall send a copy of the Form to the physician with the changes noted. The physician shall have one month in which to correct factual errors or dispute the information.

(b) Amendments to a physician's profile shall be made by the board when:

(1) the board receives information from non-governmental third-parties that has been verified by the board and contradicts information reported on a physician's profile;

(2) the board receives information from state or federal governmental authorities regarding criminal convictions described in §173.1(b)(18) of this title (relating to Profile Contents);

(3) the board determines that information provided on a physician's profile would violate state or federal confidentiality laws; or

(4) the board otherwise determines that information provided on a physician's profile is false or misleading.

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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Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
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For further information, please call: (512) 305-7016

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CHAPTER 196. VOLUNTARY RELINQUISHMENT OR SURRENDER OF A MEDICAL LICENSE

22 TAC §196.2, §196.3

The Texas Medical Board proposes amendments to §196.2 and §196.3, concerning Surrender Associated with Disciplinary Action and Surrender Associated with Impairment.

The amendments update the section titles for §196.4 and §167.5 which are referenced in the chapter.

Elsewhere in this issue of the *Texas Register,* the Texas Medical Board contemporaneously proposes the rule review of Chapter 196, Voluntary Relinquishment or Surrender of a Medical License.

Robert D. Simpson, General Counsel, Texas Medical Board, has determined that for the first five-year period the amendments are in effect there will be no fiscal implications to state or local government as a result of enforcing the sections as proposed. There will be no effect to individuals required to comply with the rules as proposed.

Mr. Simpson also has determined that for each year of the first five years the amendments as proposed are in effect the public benefit anticipated as a result of enforcing the sections will be updated rules. There will be no effect on small or micro businesses.

Comments on the proposal may be submitted to Sally Durocher, P.O. Box 2018, Austin, Texas 78768-2018. A public hearing will be held at a later date.

The amendments are proposed under the authority of the Texas Occupations Code Annotated, §153.001, which provides authority for the Texas Medical Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

No other statutes, articles are codes are affected by the proposal.

§196.2. Surrender Associated with Disciplinary Action.

(a) When a licensee has surrendered his or her Texas medical license in lieu of a hearing or further investigation of alleged violations of the Medical Practice Act ("the Act"), Title 3 Subtitle B Tex. Occ. Code, and its subsequent amendments, such a surrender shall be considered surrender associated with a disciplinary action.

(b) If the surrender of a Texas medical license was associated with disciplinary action, the Texas medical license shall not be returned to the licensee if the board's order on the merits of the disciplinary action is inconsistent with the return of that license. In addition to requirements set out in §196.4 of this chapter (relating to Relicensure after Relinquishment or Surrender of License [~~Reapplication for Licensure After Surrender of License~~]), a licensee who reapplies for licensure must demonstrate that the licensee's return to the practice is in the best interest of the public as defined under §167.5 of this title (relating to Best Interests of the Public [~~Reinstatement and Reissuance~~]).

(c) If a licensee agrees to permanently surrender his or her license in lieu of disciplinary action, the licensee forfeits all rights to apply for any type of licensure with the board.

§196.3. Surrender Associated with Impairment.

(a) When a licensee who, by reason of impairment from illness, drunkenness, excessive use of drugs, narcotics, chemicals, or any other type of substance or as a result of any mental or physical condition, is unable to treat patients with reasonable skill and safety and surrenders his or her Texas medical license, that surrender shall be deemed a surrender associated with impairment.

(b) A Texas medical license surrendered in accordance with this section shall not be returned to a licensee until after the board has determined that:

(1) the licensee is competent to resume practice based on adequate medical and treatment information provided to the board; and

(2) the licensee's return to the practice is in the best interest of the public as defined under §167.5 of this title (relating to Best Interests of the Public [~~Reinstatement and Reissuance~~]).

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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Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
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CHAPTER 198. UNLICENSED PRACTICE

22 TAC §198.2, §198.3

The Texas Medical Board proposes amendments to §198.2 and §198.3, concerning Complaints and Investigation of Complaints.

The amendments update the name of the Texas Department of State Health Services and provides cite to Chapter 187 of the Board's rules.

Elsewhere in this issue of the *Texas Register,* the Texas Medical Board contemporaneously proposes the rule review of Chapter 198, Unlicensed Practice.

Robert D. Simpson, General Counsel, Texas Medical Board, has determined that for the first five-year period the amendments are in effect there will be no fiscal implications to state or local government as a result of enforcing the sections as proposed. There will be no effect to individuals required to comply with the rules as proposed.

Mr. Simpson also has determined that for each year of the first five years the amendments as proposed are in effect the public benefit anticipated as a result of enforcing the sections will be updated rules. There will be no effect on small or micro businesses.

Comments on the proposal may be submitted to Sally Durocher, P.O. Box 2018, Austin, Texas 78768-2018. A public hearing will be held at a later date.

The amendments are proposed under the authority of the Texas Occupations Code Annotated, §153.001, which provides authority for the Texas Medical Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

No other statutes, articles are codes are affected by the proposal.

§198.2. Complaints.

(a) Complaints to the board regarding the unlicensed practice of medicine and other violations of the Medical Practice Act, a rule adopted by the board, or another statute relating to the practice of medicine by a person who is not licensed by the board or the performance of any medical procedure without the required permit, registration, or license shall be routed to one or more of the following for appropriate handling including further investigation, cease and desist proceedings, criminal prosecution, and/or injunctive relief:

(1) the Investigation Division of the Board;

(2) the Office of the Attorney General;

(3) the Texas Department of Public Safety;

(4) the United States Drug Enforcement Administration;

(5) the Texas Department of State Health Services [~~Health~~];

(6) the local district or county attorney's office with jurisdiction;

(7) the local law enforcement agency;

(8) any state or federal licensing board or other agency which maintains jurisdiction over a person who is the subject of the complaint.

(b) In any instance in which the board may have concurrent jurisdiction with another agency over the subject of a complaint under this section, the board may pursue further investigation and appropriate action before or after routing the complaint to another agency.

(c) The routing of a complaint to another agency as provided by this section shall be in writing unless to do so is likely to jeopardize any further investigation, prosecution, or injunctive relief.

§198.3. Investigation of Complaints.

(a) A complaint or information that a person has committed a violation under this Chapter shall be processed in a manner similar to a complaint against a licensee (see Chapter 178 of this title (relating to Complaints)).

(b) After sufficient information and evidence has been gathered, a committee of board employees designated by the Executive Director, which may include the Executive Director, shall determine whether the information and evidence gathered indicate that a violation has occurred.

(c) If the committee of board employees determines that the information and evidence gathered indicate that a violation has occurred, the committee may recommend that a formal complaint be filed with the State Office of Administrative Hearings, providing notice and opportunity for a hearing as provided in Chapter 187, Subchapter C of this title (relating to Formal Board Proceedings at SOAH).

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-200704025
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
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For further information, please call: (512) 305-7016

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CHAPTER 199. PUBLIC INFORMATION

22 TAC §§199.1, 199.3 - 199.5

The Texas Medical Board proposes amendments to §§199.1 and 199.3 - 199.5, concerning Public Information.

The amendments provide that the Public Information committee is responsible for the Board's website, update the names of the Texas Medical Board, correctly cites to the Office of the Attorney General in relation to charges for copies of public records, and specifies that physicians who have any ownership interested in a niche hospital must report that interest to the Department of State Health Services.

Elsewhere in this issue of the *Texas Register,* the Texas Medical Board contemporaneously proposes the rule review of Chapter 199, Public Information.

Robert D. Simpson, General Counsel, Texas Medical Board, has determined that for the first five-year period the amendments are in effect there will be no fiscal implications to state or local government as a result of enforcing the sections as proposed. There will be no effect to individuals required to comply with the rules as proposed.

Mr. Simpson also has determined that for each year of the first five years the amendments as proposed are in effect the public benefit anticipated as a result of enforcing the sections will be updated rules. There will be no effect on small or micro businesses.

Comments on the proposal may be submitted to Sally Durocher, P.O. Box 2018, Austin, Texas 78768-2018. A public hearing will be held at a later date.

The amendments are proposed under the authority of the Texas Occupations Code Annotated, §153.001, which provides authority for the Texas Medical Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

No other statutes, articles are codes are affected by the proposal.

§199.1. Public Information/Profile Committee.

(a) The board shall maintain the Public Information/Profile Committee as a standing and permanent committee of the board.

(b) As set forth in Chapter 161 of this title (relating to General Provisions), the responsibilities and authority of the Public Information/Profile Committee include those duties and powers set forth below and in this chapter, as well as such other responsibilities and authority which the board from time to time may delegate:

(1) develop informational brochures for distribution to the public;

(2) review and make recommendations to the board in regard to press releases, newsletters, and other publications;

(3) exhibit display booths at conventions;

(4) study and make recommendations to the board regarding all aspects of public information or public relations;

(5) make recommendations to the board regarding matters brought to the attention of the Public Information/Profile Committee; and [.]

(6) maintain a website that includes information required by statute and that is easily accessible to the public.

§199.3. Requests for Information.

(a) The public may obtain copies of board newsletters, brochures, pamphlets, press releases and other board publications by written request to the attention of the Public Information/Profile Committee at the board's current mailing address or by electronic mail to the board's designated email address [~~public information officer~~].

(b) Public records of the board may be obtained to the extent allowed by law through a written request pursuant to the Public Information Act of Texas submitted to the attention of the Manager, Public Information at the board's current mailing address, by fax, or by electronic mail to the board's designated email address.

(c) The provision of written materials or records provided pursuant to a request made under this chapter shall be subject to applicable charges under this title and state law.

§199.4. Charges for Copies of Public Records.

(a) Charges. The charge to any person requesting copies of any public record of the Texas Medical Board [~~State Board of Medical Examiners~~] will be the charges established by the Office of the Attorney General [~~Texas Building and Procurement Commission~~].

(b) Routine items. All charges for routinely requested items shall be based upon the charges established by the Office of the Attorney General [~~Texas Building and Procurement Commission~~]. A current price list may be requested from the Customer Affairs Division of the Board. Upon written request, the board shall provide copies of routinely requested items, which shall include, but not be limited to, the following:

(1) Board Rules;

(2) Medical Practice Act;

(3) Microfiche with complete physician information:

(A) individual order;

(B) year subscription;

(4) New Physician List:

(A) list;

(B) year subscription;

(5) Physician Directory;

(6) Special Request:

(A) customized mailing list and labels;

(B) computer/electronic media:

(i) computer tape;

(ii) floppy disk.

(c) Certified copies. Upon written request, the Texas Medical Board [~~State Board of Medical Examiners~~] will certify any public records of the board. The cost for certifying copies of public records provided pursuant to the Texas Public Information [~~Open Records~~] Act shall be $5.00 per record or document. This cost shall be in addition to any other costs charged for providing the requested document or record, including, but not limited to, copying, retrieving, or mailing of the document or record.

(d) Waiver of charges. Copies of public records shall be furnished without charge or at a reduced charge if the executive director determines that waiver or reduction of the fee is in the public interest, and that furnishing the information can be considered as primarily benefiting the general public.

§199.5. Notice of Ownership Interest in a Niche Hospital.

(a) A physician shall notify the Department of State Health Services of any [~~an~~] ownership interest held by the physician in a niche hospital as required by §162.052 of the Act.

(b) In this section, "niche hospital," as defined by §105.002, Tex. Occ. Code, means a hospital that:

(1) classifies at least two-thirds of the hospital's Medicare patients or, if data is available, all patients:

(A) in not more than two major diagnosis-related groups; or

(B) in surgical diagnosis-related groups;

(2) specializes in one or more of the following areas:

(A) cardiac;

(B) orthopedics;

(C) surgery; or

(D) women's health; and

(3) is not:

(A) a public hospital;

(B) 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

(C) a hospital with fewer than 10 claims per bed per year.

(c) The board hereby adopts by reference the Disclosure and Consent Form, which shall be published on the board's web site and may be examined and copies obtained at the offices of the 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-200704026
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 305-7016

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PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 295. PHARMACISTS

22 TAC §295.8

The Texas State Board of Pharmacy proposes amendments to §295.8, concerning Continuing Education Requirements. The proposed amendments, if adopted, will allow pharmacist to obtain continuing education credit for taking and successfully passing the initial Geriatric Pharmacy Practice certification examination administered by the Commission for Certification in Geriatric Pharmacy.

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 rule.

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 rule will be to ensure pharmacists have obtained continuing education credit relative to the practice of pharmacy. There is no fiscal impact for individuals, small or large businesses or to other entities which are required to comply with this amended 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 5:00 p.m., October 15, 2007.

The amendments are proposed under §§551.002, 554.051, and 559.052 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 §559.052 as authorizing the Board to adopt rules regarding the approval of providers of continuing education.

The statutes affected by the amendments: Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§295.8. Continuing Education Requirements.

(a) - (d) (No change.)

(e) Approved Programs.

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

(9) Pharmacists shall receive credit for three contact hours (0.3 CEUs) toward their continuing education requirements for taking and successfully passing the initial Geriatric Pharmacy Practice certification examination administered by the Commission for Certification in Geriatric Pharmacy. Proof of successfully passing the examination shall be a certificate issued by the Commission for Certification in Geriatric Pharmacy.

(10) [~~(9)~~] Upon demonstrated need the board may establish criteria to approve programs presented by non-ACPE approved providers.

(f) - (g) (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 August 29, 2007.

TRD-200703995
Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 305-8028

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PART 27. BOARD OF TAX PROFESSIONAL EXAMINERS

CHAPTER 623. REGISTRATION AND CERTIFICATION

22 TAC §623.4

The Board of Tax Professional Examiners proposes an amendment to §623.4 Persons Permitted To Register. This amendment is intended to ensure that there is a thorough review of the past behavior of certain persons who may reapply for registration by the Board after a period of "inactivity."

Mr. David Montoya, Executive Director for the Board of Tax Professional Examiners has determined the probable economic cost to persons required to comply with the amendment for the first five years will be zero because the amendment merely provides for a more thorough review of the reinstatement application.

Mr. David Montoya also has determined that for each year of the first five years the amendment as proposed is in effect the public benefit anticipated as a result of enforcing the section will be to conform the board rule to better protect the public. There will be no effect on small or micro businesses.

The Board requests comments on the substance and effect of the proposed amendment from any interested person. Comments must be received at the Board no later than noon on October 28, 2007. Comments should be addressed to David E. Montoya, Executive Director, Texas State Board of Tax Professional Examiners, 333 Guadalupe, Tower II, Suite 520, Austin, Texas 78701 or faxed to his attention at (512) 305-7304.

The Board specifically invites comments from the public on the issues of whether or not the proposed amendment will have an adverse economic effect on small business; if the amendment is believed to have such an effect, then how may the Board legally and feasibly reduce that effect considering the purpose of the statute under which the amendment is to be adopted; and if the amendment is believed to have such an effect.

The amendment is proposed under the authority of Texas Civil Statutes Occupations Code, Chapter 1151 Property Taxation Professional Certification Act, which provide the Board of Tax Professional Examiners with the authority to promulgate rules consistent with the Statute.

No other article, statute or code is affected by this proposed amendment.

§623.4. Persons Permitted To Register.

(a) No person shall be permitted to register who is not required to register. There shall be no registration categories involving associates, nonparticipating, etc. Registrants must be actively engaged in appraising, assessing/collecting, or collecting for an appraisal district or taxing unit in the state.

(b) If a registrant becomes inactive under subsection (a) of this section because the registrant in a criminal case pleads guilty, is convicted, or is given deferred adjudication of an offense or offenses that if pursued through the complaint procedure would have resulted in revocation, the board may upon complaint brought before it by the executive director, a board member, or a citizen of the state revoke the registrants license so that the registrant may not apply for registration for a period of three years as provided in §629.4(a). Such a revocation procedure shall be summary in nature with the registrant being given an opportunity to appear before a meeting of the full board with counsel.

(c) If it comes to the attention of a board member or the executive director that a registrant may have committed an act that could have resulted in disciplinary action by the board, but the registrant is inactive as a result of the operation of subsection (a) of this section, the board may proceed through its regular complaint and disciplinary procedures to determine whether an appropriate discipline should be recorded in the registrant's file at the board's office.

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 August 30, 2007.

TRD-200704021
David Montoya
Executive Director
Board of Tax Professional Examiners
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 305-7300

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TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 157. EMERGENCY MEDICAL CARE

SUBCHAPTER C. EMERGENCY MEDICAL SERVICES TRAINING AND COURSE APPROVAL

25 TAC §157.39

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes new §157.39, concerning the regulation of emergency medical services (EMS) providers.

BACKGROUND AND PURPOSE

The new section will create an EMS training program that affiliated EMS personnel may use to assure and maintain ongoing professional competency. Health and Safety Code, Chapter 773, Subchapter A, requires the department to approve EMS training programs and to regulate EMS providers and EMS personnel in their providing for the prompt and efficient transportation of sick and injured patients, after necessary stabilization, and to encourage public access to that transportation in each area of the state. This rule was developed with input from EMS stakeholders and the Governor's EMS and Trauma Advisory Council (GETAC).

SECTION-BY-SECTION SUMMARY

This section establishes eligibility requirements and minimum training standards that a Texas licensed EMS provider must have and maintain to receive approval by the department for the provider to conduct a Comprehensive Clinical Management Program (CCMP) for Texas certified or licensed EMS personnel employed by or affiliated with that EMS provider, such that those personnel can become recertified or relicensed pursuant to §157.34(b)(5) of this title. The training program will assure that EMS personnel affiliated with the EMS provider conducting the CCMP will receive continuing EMS education, quality improvement, intensified individualized monitoring, mentoring,

assessment and ongoing professional development as required by the standards outlined in this section.

FISCAL NOTE

Renee Clack, Section Director, Health Care Quality Section, has determined that for each year of the first five years the section is in effect, there will be no fiscal implications to state or local governments as a result of enforcing or administering the section as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Clack has also determined that there will be no effect on small businesses or micro-businesses required to comply with the section as proposed. This was determined by interpretation of the rule that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the section. This is a completely voluntary option for EMS recertification and there are no anticipated economic costs to persons not wishing to comply with the section as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Clack has also determined that for each year of the first five years the section is in effect, the public will benefit from adoption of the section. The public benefit anticipated as a result of enforcing or administering the section is to improve public health and safety through the encouragement of improvements to EMS personnel selection and training practices, and enhanced medical direction interaction.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed new rule does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Steve Janda, Director, Office of EMS/Trauma Systems Coordination, Health Care Quality Section, Division of Regulatory Services, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, (512) 834-6700 or by email to Steve.Janda@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rule has been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The new section is authorized by Health and Safety Code, §773.071, which allows the department to set fees in amounts necessary for the department to administer this subchapter; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize 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.

The proposed new section affects the Health and Safety Code, Chapters 773, and 1001; and Government Code, Chapter 531.

§157.39. Comprehensive Clinical Management Program Approval.

(a) Purpose and Scope. This section establishes eligibility requirements and minimum training standards that a Texas licensed emergency medical services (EMS) provider must have and maintain to receive approval by the department for the provider to conduct a Comprehensive Clinical Management Program for Texas certified or licensed EMS personnel employed by or affiliated with that EMS provider, such that those personnel can become recertified or relicensed pursuant to §157.34(b)(5) of this title (relating to Recertification). The program will assure that EMS personnel affiliated with the EMS provider conducting the program will receive continuing EMS education, quality improvement, intensified individualized monitoring, mentoring, assessment and ongoing professional development as required by the standards outlined in this section.

(b) Definitions.

(1) CCMP--A comprehensive clinical management program is a recertification training program conducted by a licensed EMS provider for EMS personnel employed by or affiliated with the EMS provider such that the EMS personnel can meet recertification or relicensure requirements as outlined in §157.34(b)(5) of this title.

(2) CCMP Coordinator--Person responsible for the administrative functions of the CCMP program. However, the EMS provider, approved to conduct a CCMP, is the person or entity having the ultimate and overall responsibility for continually meeting state requirements for CCMP approval.

(3) Credentialing Process--The process by which an EMS provider continually verifies and assesses the qualifications and competencies of EMS personnel to provide patient care services.

(4) CCMP Survey Organization--A department recognized organization, which manages a CCMP survey team comprised of members as described and referenced in subsection (f) of this section for the purpose of conducting a survey, based upon the standards outlined in this section, of EMS providers seeking CCMP approval.

(5) Preceptor--A person who holds a department EMS personnel certificate or license or other licensed medical professional approved by the medical director and who is employed by or volunteers for an EMS provider to train and evaluate EMS personnel.

(6) Quality Improvement Process--An ongoing system that includes retrospective review, concurrent review, and prospective forecasting of clinical care. Quality improvement also combines a circular response through measurement of identified goals and sentinel events identifying opportunities for improvement, reeducation, process design, and measurement of corrective efforts.

(7) Self Study--A document developed by the EMS provider that outlines its planning, preparation and qualifications to conduct a CCMP and include 6 months of operational data.

(8) Survey--The onsite visit(s) conducted by a department recognized CCMP survey organization that evaluates an EMS provider applying for department approval to conduct a CCMP.

(9) Sentinel Event--An unexpected event that triggers, or has the potential to trigger, an immediate investigation and/or response. This event usually relates to the care of a patient or the well-being of EMS personnel, such that the event causes or has the potential to cause death, serious physical or psychological injury to either the patient or the EMS personnel or the public.

(c) CCMP Eligibility Requirements.

(1) The applicant must hold a current Texas EMS provider license, continuously valid for at least 5 years prior to the date of the application.

(2) The applicant must not have received a department disciplinary sanction as an EMS provider, not including a reprimand or an administrative penalty of $2000 or less, during the 2 years immediately preceding the application filing date.

(3) Any physician who the applicant has employed or contracted with to function as its medical director or as its full-time or part-time consultant, must be in good standing with the Texas Medical Board or predecessor agency to practice medicine in Texas.

(4) A person holding more than one EMS provider license that is applying for department approval to conduct a CCMP shall be required to apply separately for each of its licenses. A CCMP approval will only be allowed per one EMS provider license. A CCMP may not extend beyond one EMS provider license and its affiliated First Responder Organization(s).

(5) Although an EMS provider approved to conduct a CCMP may require the EMS personnel, employed by or affiliated with that provider, to participate in and to meet the objectives of its own CCMP, those personnel may still utilize another option, listed in §157.34(b) of this title, to achieve individual EMS personnel state recertification or relicensure.

(6) The applicant must have submitted no less than two years of required data, prior to the initial CCMP survey, to the Texas EMS/Trauma Registry.

(d) Application Process for CCMP Approval.

(1) A sufficiently complete application shall include:

(A) a full non-refundable CCMP approval application fee payment of $60.00;

(B) department application form with all fields correctly and legibly filled in, dated, and signed with original signatures of the EMS director, CCMP coordinator, and EMS provider's medical director; and

(C) all required documents to include an accurate and complete CCMP self-study. This self-study shall be submitted in an electronic format as required and described by the department and shall sufficiently and accurately address those topics outlined in subsection (h) of this section.

(2) Initial Application Form Review Period. Within 30 days from the date the department receives an initial written application for CCMP approval from an applicant, the department will send to the applicant a written notice that either the application form is complete and accepted for filing, or the application form is incomplete, and noting the application's deficiencies and the additional information required for the application to be accepted for filing.

(3) Continuing Application Form Review Period. Within 14 days from the date that the department receives any written information from the applicant that attempts to respond to an earlier department notice of any application deficiencies and notice of the need for additional information to resolve the deficiencies, the department will send the applicant a written notice that either the application form is finally complete and accepted for filing or that the application form is still incomplete, and specifying any remaining application deficiencies and the additional information required for it to be accepted for filing.

(4) Final Application Form Review Period. Within 14 days from the date that the department receives from the applicant the last item or piece of information to resolve all previously noted deficiencies necessary to complete the application, the department will send written notice to the applicant that the application is finally complete and accepted for filing.

(5) Failure to Correct Application Form Deficiencies. If the department does not receive from an applicant the items or information requested by the department to correct the deficiencies in the application form by the 10th day after the date that the department has sent written notice to the applicant noting that the application form is incomplete for filing and noting the application's deficiencies and the additional information required for it to be accepted for filing, then the application is deemed to be withdrawn and void. The application fee will not be refunded.

(6) Initiation of Survey. After the department notifies applicant that the application form is sufficiently complete and is accepted for filing, the EMS provider can initiate the survey process to be conducted by a department recognized CCMP survey organization.

(7) Final Period for Full Application Review. The final period for full application review will begin on the date that the department timely receives from the applicant's survey organization a true and correct written survey report, the department's review of which will be the last stage of the application review process, and end on the date that the department sends written notice to the applicant that the application for CCMP approval is granted, or that it proposes to deny the application. This period is 60 days.

(8) CCMP Approval Period. The department's grant of approval to an EMS provider to conduct a CCMP will be valid for four years from the date that approval is granted, unless the EMS provider later surrenders its CCMP approval or the department revokes the approval.

(e) Application Process to Renew CCMP Approval.

(1) No later than the 120th day prior to the expiration date of the existing CCMP approval, an EMS provider, who is requesting renewal of CCMP approval, shall:

(A) timely file a sufficiently completed renewal application form according to the application filing process, as described in subsection (d) of this section;

(B) have been timely re-surveyed by a department recognized CCMP survey organization, in advance to allow for report submission described in subparagraph (C) of this paragraph; and

(C) ensure that the CCMP survey organization, that has conducted the survey, has filed with the department and that the department has received from the survey organization a complete survey report.

(2) If a renewal applicant meets the requirements in subsection (1) of this section no later than the 120th day prior to the expiration date of its existing CCMP approval, the existing CCMP approval does not expire until the applicant's eligibility for renewal of its CCMP approval has been finally determined, as described in Texas Government Code, §2001.054. If the department provides the applicant with a written notice proposing the denial of its renewal application or placement of limitations upon the renewal of approval, and if the department timely receives from the applicant a written request for an administrative appeal hearing to contest the proposed denial or limitation, the existing CCMP approval does not expire until the last day for the applicant to seek a state district court judicial review of the agency order or a later date fixed by order of the reviewing court.

(3) If a renewal applicant fails to meet the requirements in subsection (1) of this section, no later than 120 days prior to the expiration date of its existing CCMP approval, the existing CCMP approval expires on its expiration date.

(4) Any EMS personnel that are participating in the applicant's existing CCMP may lose their eligibility to renew their individual EMS certifications or licenses under §157.34(b)(5) of this title, after the expiration date of the existing approved CCMP within which the EMS personnel are participating. If a CCMP approval expires, as set forth in paragraphs (2) or (3) of this subsection, EMS personnel who continue to participate with that CCMP after its expiration date will no longer be allowed credit toward continuing education hours needed for certification or licensure renewal, unless approved by the department.

(f) CCMP Survey.

(1) The applicant shall seek review and approval of its self-study by a department recognized CCMP survey organization.

(2) The applicant shall notify the department of the date the survey will begin, the name of the CCMP survey organization, the composition of the survey team, and the names of the survey team members, no later than the 30th day prior to the date the CCMP survey will begin.

(3) The applicant shall be responsible for any cost and expenses associated with the survey.

(4) The department, at its discretion, may assign a department staff member and/or appoint an observer to accompany the survey team.

(5) The survey team shall contain members that have a multi-disciplinary background to include at a minimum: one EMS medical director, one EMS educator and one EMS administrator. The department may require additional surveyors and surveyors with other professional backgrounds, depending upon, but not limited to, the type of EMS provider, the kind of population it serves, and factors noted in the self-study. If such is required, the department will notify the applicant of the additional required surveyors within 20 days after the date that the department has notified the applicant that its application is complete and accepted for filing.

(6) All members of the survey team, except department staff, shall come from a Trauma Service Area that the applicant is not affiliated with and at least 100 miles from the provider unless otherwise approved by the department at least 20 days before the date the survey is to begin. There shall be no direct business or patient care relationship or any potential conflict of interest between the CCMP survey members, or any of the individual survey members' places of employment or affiliation with a volunteer EMS provider, and the applicant being surveyed. The survey team shall not be composed solely with members from a single EMS provider.

(7) Department recognized survey organization team members at minimum shall:

(A) have at least five years experience in active management and leadership of an EMS system using CCMP principles;

(B) be currently employed with or volunteering for, and be actively managing within an EMS system using CCMP principles;

(C) have adequate direct experience in assisting an EMS provider in preparing for a CCMP survey and in obtaining CCMP approval; and

(D) have completed a department-approved CCMP survey course and/or participation in a survey internship.

(8) The department at its discretion may exempt survey team members from having to meet the requirements noted in paragraph (7)(A), (B) or (C) of this subsection, if the number of qualified survey team members in the applicant's general geographical area is inadequate to form a survey team. The CCMP survey organization must make a written request showing sufficient cause for the department to grant an exemption.

(9) The survey organization with its survey team members shall professionally and accurately evaluate and make written findings of the EMS provider's ability to effectively meet and maintain CCMP standards described in subsection (h) of this section.

(g) Survey Documentation and Reporting Timetable.

(1) The survey organization shall utilize the department's CCMP survey form and shall provide the department and the provider with an accurate and complete written survey report, signed by all survey team members, regarding its evaluation of the applicant's compliance with CCMP standards, no later than 30th calendar day after the completion date of the survey.

(2) The CCMP survey(s), and the resulting survey documentation, and the applicant's CCMP survey organization's submission of the survey report and related documentation to the department shall be completed no later than two years after the date the department sent notice to the applicant that its application was accepted for filing. Failure to timely complete all of the above within two years from the date that the department sent notice to the applicant that its application was accepted for filing will be deemed to be a withdrawal of the EMS provider's application for CCMP approval.

(3) The department reserves the right to request from the applicant, and the applicant shall be obligated to produce no later than the 10th day after having received such request, true and correct copies of any survey reports that the applicant received from its survey organization related to any initial surveys, conducted prior to any final survey.

(4) CCMP Final Survey Report. The survey report, completed by the department recognized CCMP survey organization, shall accurately document the survey organization's findings and its evaluation of the EMS provider's ability to effectively meet the minimum standards required to obtain and to maintain CCMP department approval as outlined in subsection (h) of this section.

(h) CCMP Minimum Standards. To receive and maintain department approval to conduct a CCMP, an EMS provider shall:

(1) assure that an initial assessment of new EMS personnel has been conducted by providing documentation of:

(A) a written assessment of didactic knowledge evaluation, specific to the certification level of the applicant and focusing on the clinical information (evaluation cannot be the department or

NREMT exam, and should utilize numeric scoring - not pass/fail - to assess individuals' level of preparedness);

(B) a situation-based practical evaluation;

(C) a background investigation process of EMS personnel, which includes verification of certification/licensure and administrative/disciplinary history through the department, work history and driving record;

(D) a detailed job description; and

(E) a screening process to ensure the minimum requirements are met, and which includes significant medical director involvement.

(2) credential EMS personnel by providing documentation of:

(A) a state certification/licensure verification process;

(B) a process for EMS personnel to demonstrate skills proficiency to the satisfaction of the medical director;

(C) a process for reintegration (i.e. bringing an individual from inactive or administrative status back into active practice in the field);

(D) a process for bi-annual field evaluation by a preceptor (field training officer or similar position) which includes demonstration of adequate patient care and scene control skills, appropriate conduct for EMS personnel, etc.; and

(E) a policy that defines the EMS personnel covered by the CCMP program (only individuals credentialed by the medical director will be eligible for renewal through §157.34(b)(5) of this title).

(3) assure and maintain a preceptor selection, development and training process; developed with the medical director's input and approval.

(4) assure EMS personnel internship by providing documentation of:

(A) a process in which interns ride as a third person until the preceptor establishes the intern has met pre-established competencies as defined by the medical director;

(B) a process in which interns ride as the second person until the preceptor establishes the intern has met prerequisites for independent duty as determined by the medical director;

(C) a process in which the intern must demonstrate proficiency to at least two different preceptors;

(D) a process in which the intern evaluates the internship program; and

(E) a process in which the medical director reviews and ensures that all predetermined competencies are met before being released from internship.

(5) assure and maintain professional development of EMS personnel by maintaining and providing documentation:

(A) of professional development training of EMS personnel in the following amounts per year: EMT-P--24 hours, EMT-I--20 hours, EMT--16 hours, ECA--10 hours;

(B) that other staff (flight nurses and communications personnel) are required to obtain at least the minimum continuing education hours as directed by the appropriate certifying or licensing authority;

(C) that EMS personnel receive continuing education on at least a semiannual or quarterly basis;

(D) that the continuing education instruction spans the three learning domains which include cognitive, affective and psychomotor;

(E) that demonstrates programmatic strengths and performance improvement plans for weaknesses;

(F) that the continuing education clinical content is defined and approved by the medical director;

(G) that 50% of the continuing education is in-person training; and

(H) of consistent instructional delivery by all instructors.

(6) assure and maintain protocol/standard of care management by providing documentation of:

(A) ongoing protocol review, updated according to current literature, practice techniques, executed and approved by the medical director;

(B) a process for assessing the relative benefit from protocol revisions;

(C) a process for protocol knowledge assessment among EMS personnel protocol assessment that reflects the ongoing protocol review and revision, with structure and content defined and approved by the medical director, and a defined remediation process with established timelines;

(D) a process for protocol criteria to be jointly defined by the medical director and EMS provider administration; and

(E) a reassessment/re-education process and timeline that clearly identifies the criteria for identification of weakness and successful completion of re-education; or revocation of credentials if unsuccessful.

(7) assure and maintain a quality improvement program by providing documentation of:

(A) a five component problem-solving process with the following components: assessment, goal setting, plan development, intervention, and progress evaluation;

(B) an assessment of the provider's daily activities;

(C) measurable clinical indicators that are regularly assessed for compliance with established thresholds;

(D) an appropriate, organized and prioritized monitoring and evaluation system for compliance with documentation standards, correct protocol selection and appropriate patient care;

(E) assessment of key performance indicators such as personnel/staffing, response and averaging with correct statistical monitoring, clinical care (skills performance, protocol selection, patient assessment, etc.), customer relations program, education, administrative/operational policies;

(F) a monthly random chart review of all runs (at least 5% or 30, whichever is greater) for compliance with documentation standards, correct protocol selection, and appropriate patient care;

(G) an annual cardiac arrest survival analysis in accordance with current acceptable criteria; and

(H) tracking individual performance of skills (5 minimum), appropriate for that level of certification or licensure, for each EMS personnel.

(8) assure and maintain a complaint resolution process/management by providing documentation of:

(A) a centralized location for receiving complaints;

(B) an established triage process to appropriately direct complaint resolution to potential disciplinary or quality improvement avenues;

(C) a process that ensures the timely reporting of any rule or law violations to appropriate licensing and government authorities; and

(D) a process to track/trend the nature of each complaint and feed data into a quality improvement program.

(9) assure and maintain a system to respond to sentinel event response process/management; by providing documentation of:

(A) a process to appropriately direct the response to emergency problems such as equipment failures, supply deficiency, medication errors, fleet failures, etc.;

(B) appropriate record-keeping and tracking of sentinel events; and

(C) a process to investigate sentinel events which involves the appropriate parties.

(10) assure and maintain an ongoing corrective action process by providing documentation of:

(A) annual documentation of the results of the quality improvement efforts and formal complaint tracking process, including content of continuing education or individual training sessions to resolve identified deficiencies;

(B) evidence to resolve and reassess identified deficiencies;

(C) a process to determine whether deficiencies are individual or system oriented;

(D) a developed reporting structure that includes a public performance report;

(E) a policy and methods regarding privilege/confidentiality;

(F) a process of remediation and improvement strategies which comply with DSHS continuing education requirements, as appropriate; and

(G) evidence of medical director involvement in the process.

(11) assure committee(s) are established and maintained to identify, plan, implement and evaluate opportunities to improve performance in all areas of the EMS system.

(12) assure that the medical director qualifications, experience, involvement and responsibilities are maintained by providing documentation that the medical director:

(A) is registered as the EMS provider's medical director with the department;

(B) meets requirements of 22 TAC, Chapter 197 (relating to Emergency Medical Service) of the Texas Medical Board;

(C) is an active participant in the local Regional Advisory Committee; and

(D) has completed a course in EMS medical direction.

(13) assure that the CCMP coordinator qualifications, experience, involvement and responsibilities are maintained by providing documentation that:

(A) the CCMP coordinator is responsible for the administrative functions of the CCMP program;

(B) the dedication of staff time is sufficient to fulfill the programmatic requirements of the CCMP;

(C) a CCMP organizational chart clearly describes the administrative reporting structure of the CCMP program;

(D) there is evidence to demonstrate that quality improvement experience and/or training is sufficient to implement and maintain CCMP standards; and

(E) shall complete a department approved CCMP workshop of at least 8 hours.

(i) Probation, Suspension, Revocation or Denial of Initial or Renewal CCMP Approval. The department may probate, suspend, revoke, or deny initial or renewal approval for an EMS provider to conduct a CCMP for, but not limited to, the following noted reasons:

(1) the EMS provider fails to meet or maintain the CCMP minimum standards or the eligibility requirements, outlined in this section;

(2) the EMS Provider fails to meet or maintain those responsibilities required or standards, outlined in §157.11 of this title (relating to Requirements for an EMS Provider);

(3) the EMS provider falsifies or makes misrepresentations in any documentations communications regarding its applications seeking department approval to conduct a CCMP;

(4) the provider falsifies or makes misrepresentations in any documentations or communications regarding its conducting a CCMP; or

(5) the EMS provider is found to have committed any of the violations, outlined in §157.16 of this title (relating to Emergency Suspension, Suspension, Probation, Revocation or Denial of a Provider License) that serves as a basis for such department disciplinary actions as: a reprimand, a monetary administrative penalty assessment, EMS provider license suspension, probated suspension of an EMS provider license, revocation of license, emergency suspension of license.

(j) Appeal Procedure for Proposed Denial, Probated Suspension, Suspension, or Revocation of CCMP Approval.

(1) If the department proposes to deny, suspend, or revoke its approval given for an EMS provider to conduct a CCMP, the department will send written notification of such to the EMS provider's last known address as shown in the current records of the department. The notice will state the alleged facts or conduct to warrant the proposed action and state that the EMS provider may request an administrative hearing.

(2) An EMS provider's request for an administrative appeal hearing to contest the proposed action shall be in writing and submitted to the department within 15 days after the date that the department sent written notice to the EMS provider of the department's proposed action. The appeal hearing shall be conducted pursuant to the Administrative Procedure Act, Government Code, Chapter 2001.

(3) If the department does not receive a written notice of its request for an administrative appeal hearing from the EMS provider by the 15th day after the date the department sent written notice to the EMS provider of the department's proposed action, the EMS provider is deemed to have waived the opportunity for a hearing and the department may take the proposed action.

(k) Probation. The department may probate the suspension of approval of a CCMP and specify terms and conditions of any probated suspension accessed.

(l) Surrender of CCMP Approval.

(1) An EMS provider shall use a department approved surrender form to document its surrender to the department of its CCMP approval.

(2) An EMS provider's surrender of a CCMP approval to the department shall not deprive the department of jurisdiction in regard to any disciplinary action against the EMS provider.

(3) In the event that any department proposed disciplinary against the EMS provider is pending or is reasonably imminent, the EMS provider must acknowledge that the surrender of its CCMP approval constitutes a plea of "no contest" to the allegations upon which the proposed disciplinary action is predicated.

(m) Reapplication After Surrender, Denial, or Revocation. An EMS provider, whose EMS provider license or approval to conduct a CCMP has either been surrendered while disciplinary action is pending or is reasonably imminent or which has been denied or revoked, cannot apply for, nor receive, approval to conduct a CCMP until 2 years after the date of the denial, revocation or such surrender of the EMS provider license or CCMP approval. An EMS provider who files an application for CCMP approval at least 2 years after the date of such surrender, denial or revocation of its previous EMS provider license or CCMP approval, shall provide evidence, and have the burden to show, that the reasons for the earlier denial, revocation, or such surrender of its previous EMS provider license or CCMP approval, no longer exists.

(n) Notification of Disposition. A summary of the department's order, outlining the final disposition of any proposed disciplinary action and the basis for such may be placed upon the department's website. A copy of such order may be sent to the licensed EMS provider, and the medical director.

(o) Medical Director Attestation of CCMP Participation. With regard to EMS personnel, employed by or affiliated with an EMS provider having approval to conduct a CCMP, the EMS provider's medical director shall timely provide to such EMS personnel a document, signed and dated by the medical director, attesting to such EMS personnel's participation in that CCMP.

(1) The document shall acknowledge that the EMS personnel is currently participating in the CCMP and shall specify the amount of time, including the beginning date that the EMS personnel participated in the CCMP.

(2) For those personnel who leave the CCMP the medical director within 30 days of their departure (or sooner, if needed) shall provide to the EMS personnel documentation, attesting to such EMS personnel's participation in that CCMP and attesting to the amount of time, including the beginning date and ending date, that the EMS personnel participated in the CCMP.

(3) Those EMS personnel, who have departed from an approved CCMP and who are making application for recertification or relicensure, wholly or partly through §157.34(b)(5) of this title, utilizing a medical director's signed document that attests to the EMS personnel's participation in a CCMP, will be given by the department a prorated continuing education credit, in six month increments, for the amount of time the person was participating in a CCMP.

(4) Those continuing education credit hours, used to satisfy those continuing education requirements of a CCMP by EMS personnel who have departed from that CCMP, cannot be credited or used again to supplement any remaining number of continuing education hours needed by EMS personnel to gain recertification or relicensure. Only continuing education hours gained by EMS personnel that were not used to satisfy a CCMP's requirements can be used to supplement the department's recertification or relicensure 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.

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Lisa Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 458-7111 x6972

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CHAPTER 289. RADIATION CONTROL

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes the repeal of §289.3, concerning infrasonic, sonic, and ultrasonic radiation (acoustic radiation), the proposed amendment of §289.130 concerning the radiation advisory board, the proposed amendment of §289.205, concerning hearing and enforcement procedures, the proposed repeal of §289.257, and proposed new §289.257 concerning packaging and transportation of radioactive material.

BACKGROUND AND PURPOSE

The proposed repeal of §289.3 removes an unnecessary regulation. This regulation has not been updated since 1975 and is not used in the regulatory duties of the department.

The proposed amendment to §289.130 provides corrections and clarifications due to the reorganization that created the department as well as the removal of some redundancy with the Health and Safety Code.

The proposed amendment to §289.205 provides corrections and clarifications. Information intended to clarify the definitions of severity levels of violations, the response to notices of violation, and the criteria used in elevating or reducing severity levels has been added.

The proposed repeal of and proposed new §289.257 are necessary to modify transportation requirements for shipment of radioactive material. Most of these requirements are items of compatibility with the United States Nuclear Regulatory Commission (NRC) and, as an agreement state with the NRC, Texas must adopt them.

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). Section 289.3 has been reviewed; and the department has determined that the reasons for adopting the section no longer exist, and the rule on this subject is

not needed. Sections 289.130, 289.205 and 289.257 have been reviewed; and the department has determined that the reasons for adopting these sections continue to exist because rules on these subjects are needed.

SECTION-BY-SECTION SUMMARY

The proposed repeal of §289.3 is necessary because the ultrasonic, infrasonic, and sonic radiation technology addressed in the rule is not regulated by the department. The rule has not been enforced by the department for more than 20 years.

The proposed revisions to §289.130 are necessary to delete references to the Texas Board of Health, which no longer exists and to provide the appropriate references to the Texas Health and Human Services Commission, the department, and the Railroad Commission of Texas. These changes are made in §289.130(c), §289.130(d)(1), and new §289.130(m)(1) and (2).

Information is deleted from §289.130(d) to limit repetition of information from the Health and Safety Code.

Current §289.130(e), concerning the Radiation Advisory Board review and duration section, is deleted because in 2003 the Executive Commissioner of the Health and Human Services Commission exempted the Radiation Advisory Board from abolition based on legislation that authorized the Executive Commissioner to exempt certain advisory bodies from abolition. Subsequent subsections are renumbered. The change is reflected in new §289.130(e) - (o).

Proposed new §289.130(e) adds the complete reference to the Health and Safety Code for consistency.

Proposed new §289.130(h)(2) deletes the requirement of specific efforts necessary for department staff in making the required meeting arrangements because this requirement is no longer valid.

In proposed new §289.130(k)(5)(A), reference to the "Texas Board of Health" was deleted as a correction because the Board no longer exists.

In proposed new §289.130(n), "the department" replaces "Texas Board of Health" to clarify to whom the required reports shall be filed. In addition, "Commissioner of the department or his designee" replaces "Texas Board of Health" as to whom the advisory board should file its annual report and details on the required report were eliminated to allow for flexibility.

The proposed revisions to §289.205 are necessary because the current rule did not clearly convey the requirements for responding to a notice of violation in §289.205(i) or the criteria used to elevate or reduce severity levels in §289.205(k). Throughout §289.205, the word "under" was replaced with the words "in accordance with" to comply with *Texas Register* form and style suggestions. The change is reflected in §289.205(c), (g)(1)(A), (i)(6), (j)(3)(D), (l)(3), and (m)(5).

The definition of "administrative penalty" in §289.205(b)(1) was revised to add "Texas Radiation Control" before "Act" to state the complete title of the referenced Act and "(Act)" was added after "Act" to specify the acronym that will be used throughout the section for simplification. The definitions in §289.205(b)(3) and (7) are revised to replace the word "under" with the words "in accordance with" to comply with *Texas Register* form and style suggestions.

Section §289.205(b)(12) adds the words "prepared by the department" after the word "statement" to clarify who is responsible for preparing the written statement described in this definition. In addition, the requirement for a person who receives the notice to provide a written statement is deleted within the definition because this requirement is a compliance procedure and was, therefore, moved to §289.205(i)(1) which addresses the compliance procedures.

In §289.205(i)(5) and (6), the term "enforcement conference" is deleted in the rule and replaced with "informal meeting" to reflect the definition. Section 289.205(i)(7) replaces the word "accorded" with the word "afforded" for clarification.

Section 289.205(j)(3)(C) deletes the phrase "severity levels and" in front of the word "percentages" and the phrase "of base amounts" is added after the word "percentages" as a correction so as to properly state the purpose of the regulation. The percentages in the table are the items being adjusted in this paragraph, not the severity levels. The words "for each violation" are added after the word "penalty" in §289.205(j)(3)(D) to clarify that the penalty assessed takes into account each violation. In addition, the term "Office of General Counsel" is replaced with "department" in §289.205(j)(4) to clarify who is responsible for conducting settlement negotiations.

In §289.205(k)(1)(A) - (C) clarifying language is added to assist in the understanding of categories of severity levels of violations. Section 289.205(k)(3)(A) and (B) replaces the word "Violations" with the words "Severity levels" for clarification and to be consistent with the paragraph title. In addition, §289.205(k)(3)(A)(iv) adds the words "or grossly negligent" after the word "willful" and deletes the language that attempted to explain when a violation was deemed willful in order to add clarity. A new clause is added to §289.205(k)(3)(A) and (B) to include other mitigating factors to the list of reasons when a severity level may be elevated to a higher severity level.

Concerning proposed new §289.257, the revision incorporates requirements that are items of compatibility with the NRC and Texas must adopt them. Changes from the proposed repealed rule include additional definitions, changes in the A_1 and A_2 activity levels, exempt quantities and the addition of sections regarding exemption from classification as fissile material, and general licensing information for transporting fissile material.

FISCAL IMPACT

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that, for each year of the first five-year period that the sections are in effect, there will be no fiscal implications to the state or local government as a result of enforcing and administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson has also determined that there will be no effect on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections. There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Tennyson has also determined that, for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit

anticipated as the result of administering §289.130 is to provide for the department to receive expert advice on radiation issues and, therefore, continue to protect the public from unnecessary exposure to radiation. The public benefit anticipated as a result of enforcing or administering §289.205 is to ensure continued protection of the public, workers, and the environment from unnecessary exposure to radiation by ensuring that the department is able to properly enforce the state's radiation protection rules. The public benefit anticipated as a result of enforcing or administering §289.257 is to ensure continued provision of safe, proper transportation of radioactive materials within the state of Texas in order to continue to properly protect the public, workers, and the environment from unnecessary exposure to radiation. There is no longer a public benefit from §289.3; therefore, it is being repealed.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of a state or a sector of the state.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Cindy Cardwell, Radiation Group, Policy/Standards/Quality Assurance Unit, Division for Regulatory Services, Environmental and Consumer Safety Section, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, (512) 834-6770, extension 2239, or by e-mail to Cindy.Cardwell@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

PUBLIC HEARING

A public hearing to receive comments on the proposal will be scheduled after publication in the *Texas Register* and will be held at the Department of State Health Services, Exchange Building, 8407 Wall Street, Austin, Texas 78754. The meeting date will be posted on the Radiation Control website (www.dshs.state.tx.us/radiation). Please contact Cindy Cardwell at (512) 834-6770, extension 2239, or Cindy.Cardwell@dshs.state.tx.us if you have questions.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

SUBCHAPTER A. CONTROL OF RADIATION

25 TAC §289.3

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

STATUTORY AUTHORITY

The proposed repeal is authorized by Health and Safety Code, §401.051, which provides the Executive Commissioner of the Health and Human Services Commission with authority to adopt rules and guidelines relating to the control of radiation and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. The review of the rule implements Government Code, §2001.039.

The proposed repeal affects the Health and Safety Code, Chapters 401 and 1001; and Government Code, Chapter 531.

§289.3. Control of Infrasonic, Sonic, and Ultrasonic Radiation.

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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Lisa Hernandez
General Counsel
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SUBCHAPTER C. TEXAS REGULATIONS FOR CONTROL OF RADIATION

25 TAC §289.130

STATUTORY AUTHORITY

The proposed amendment is authorized by Health and Safety Code, §401.051, which provides the Executive Commissioner of the Health and Human Services Commission with authority to adopt rules and guidelines relating to the control of radiation and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. The review of the rule implements Government Code, §2001.039.

The proposed amendment affects the Health and Safety Code, Chapters 401 and 1001; and Government Code, Chapter 531.

§289.130. Radiation Advisory Board.

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

(c) Purpose. The purpose of the board is to provide advice to the Executive Commissioner of the Texas Health and Human Services Commission (Executive Commissioner) [~~Texas Board of Health~~], the Texas Department of State Health Services' [~~Texas Department of Health's~~] (department) radiation program, the Texas Commission on Environmental Quality, the Railroad Commission of Texas, and other state entities in the area of state radiation policies and programs.

(d) Tasks.

[~~(1)~~] The board shall advise the Executive Commissioner [~~Texas Board of Health~~] in accordance with Health and Safety Code, §401.019 [~~and the department's radiation program concerning rules relating to state regulation of radiation~~].

[~~(2) The board shall:~~]

[~~(A) review and evaluate policies and programs of the state relating to radiation;~~]

[~~(B) make recommendations and furnish technical advice as may be required on matters relating to development, use, and regulation of sources of radiation to the department, the Texas Commission on Environmental Quality, the Railroad Commission of Texas, and other state entities; and~~]

[~~(C) review proposed rules and guidelines of any state agency relating to regulation of sources of radiation and recommend changes in proposed or existing rules and guidelines relating to sources of radiation.~~]

[~~(e) Review and duration. By September 1, 2007, the Texas Board of Health will initiate and complete a review of the board to determine whether a recommendation should be made to appropriate government officials to continue the board, consolidate the board with another advisory board or committee, or abolish the board.~~]

(e) [~~(f)~~] Composition. The board shall be composed of 18 members appointed by the governor. The composition of the board shall include representatives from those areas as delineated in [~~Chapter 401 of the~~] Health and Safety Code, §401.015.

(f) [~~(g)~~] Terms of office. The term of office of each member shall be six years. Members shall serve after expiration of their term until a replacement is appointed.

(1) Members shall be appointed for staggered terms so that the terms of a substantial equivalent number of members will expire at the discretion of the governor.

(2) If a vacancy occurs, a person shall be appointed by the governor to serve the unexpired portion of that term.

(g) [~~(h)~~] Officers. The board shall elect a chairman, vice-chairman and secretary at its first meeting after August 31st of each year.

(1) Each officer shall serve until the next regular election of officers.

(2) The chairman shall preside at all board meetings at which he or she is in attendance, call meetings in accordance with this section, appoint subcommittees of the board as necessary, and cause proper reports to be made to the board. The chairman may serve as an ex-officio member of any subcommittee of the board.

(3) The vice-chairman shall perform the duties of the chairman in case of the absence or disability of the chairman. In case the office of chairman becomes vacant, the vice-chairman will serve until a successor is elected to complete the unexpired portion of the term of the office of chairman.

(4) A vacancy which occurs in the offices of chairman, vice-chairman or secretary may be filled at the next board meeting.

(h) [~~(i)~~] Meetings. The board shall meet quarterly on dates set by the board to conduct board business.

(1) A special meeting may be called by the chairman or at least five members of the board.

(2) Meeting arrangements shall be made by department staff. [~~Department staff shall contact board members to determine availability for a meeting date and place.~~]

(3) The advisory board is not a "governmental body" as defined in the Open Meetings Act. However, in order to promote public participation, each meeting of the board shall be announced and conducted in accordance with the Open Meetings Act, Texas Government Code, Chapter 551, with the exception that the provisions allowing executive sessions shall not apply.

(4) Each member of the board shall be informed of a board meeting in a timely manner.

(5) A simple majority of the members of the board shall constitute a quorum for the purpose of transacting official business.

(6) The board [~~Board~~] is authorized to transact official business only when in a legally constituted meeting with quorum present.

(7) The agenda for each board meeting shall include an item entitled public comment under which any person will be allowed to address the board on matters relating to board business. The chairman may establish procedures for public comment, including a time limit on each comment.

(i) [~~(j)~~] Attendance. Members shall attend board meetings as scheduled. Members shall attend meetings of subcommittees to which the member is assigned.

(1) A member shall notify the chairman or appropriate department staff if he or she is unable to attend a scheduled meeting.

(2) It is grounds for removal from the board if a member cannot discharge the member's duties for a substantial part of the term for which the member is appointed because of illness or disability, or is absent from more than half of the board meetings during a calendar year without an excuse approved by a majority vote of the advisory board.

(3) The validity of an action of the board is not affected by the fact that it is taken when a ground for removal of a member exists.

(j) [~~(k)~~] Staff. Staff support for the board shall be provided by the department.

(k) [~~(l)~~] Procedures. Roberts Rules of Order, Newly Revised, shall be the basis of parliamentary decisions except where otherwise provided by law or rule.

(1) Any action taken by the board must be approved by a majority vote of the members present once quorum is established.

(2) Each member shall have one vote.

(3) A member may not authorize another individual to represent the member by proxy.

(4) The board shall make decisions in the discharge of its duties without discrimination based on any person's race, creed, gender, religion, national origin, age, physical condition, or economic status.

(5) Minutes of each board meeting shall be taken by department staff.

(A) A summary of the meeting shall be provided to [~~the Texas Board of Health and~~] each member of the board within 30 days of each meeting.

(B) After approval by the board, the minutes shall be signed by the secretary.

(l) [~~(m)~~] Subcommittees. The board may establish subcommittees as necessary to assist the board in carrying out its duties.

(1) The chairman shall appoint members of the board to serve on subcommittees and to act as subcommittee chairpersons. The chairman may also appoint nonmembers of the board to serve on subcommittees as the need for additional expertise arises.

(2) Subcommittees shall meet when called by the subcommittee chairperson or when so directed by the board.

(3) A subcommittee chairperson shall make regular reports to the board at each board meeting or in interim written reports as needed. The reports shall include an executive summary or minutes of each subcommittee meeting.

(m) [~~(n)~~] Statement by members.

(1) The Executive Commissioner [~~Texas Board of Health~~], the department, and the board shall not be bound in any way by any statement or action on the part of any board member except when a statement or action is in pursuit of specific instructions from the Executive Commissioner [~~Texas Board of Health~~], department, or board.

(2) The board and its members may not participate in legislative activity in the name of the Executive Commissioner [~~Texas Board of Health~~] or the department except with approval through the department's legislative process. Board members are not prohibited from representing the board's decisions, themselves, or other entities in the legislative process.

(3) A board member should not accept or solicit any benefit that might reasonably tend to influence the member in the discharge of the member's official duties.

(4) A board member should not disclose confidential information acquired through his or her board membership.

(5) A board member should not knowingly solicit, accept, or agree to accept any benefit for having exercised the member's official powers or duties in favor of another person.

(6) A board member who has a personal or private interest in a matter pending before the board shall publicly disclose the fact in a board meeting and may not vote or otherwise participate in the matter. The phrase "personal or private interest" means the board member has a direct pecuniary interest in the matter but does not include the board member's engagement in a profession, trade, or occupation when the member's interest is the same as all others similarly engaged in the profession, trade, or occupation.

(n) [~~(o)~~] Reports to the department [~~Texas Board of Health~~]. The board shall file an annual written report with the Commissioner of the department or his designee [~~Texas Board of Health~~].

[~~(1) The report shall list the meeting dates of the board and any subcommittees, the attendance records of its members, a brief description of actions taken by the board, a description of how the board has accomplished the tasks given to the board by the Texas Board of Health, the status of any rules which were recommended by the board to the Texas Board of Health, and anticipated activities of the board for the next year.~~]

[~~(2) The report shall identify the costs related to the board's existence, including the cost of department staff time spent in support of the board's activities and the source of funds used to support the board's activities.~~]

[~~(3) The report shall cover the meetings and activities in the immediate preceding 12 months and shall be filed with the Texas Board of Health each September. It shall be signed by the chairman and appropriate department staff.~~]

(o) [~~(p)~~] Reimbursement for expenses. In accordance with the requirements set forth in the Government Code, Chapter 2110, a board member may receive reimbursement for the member's expenses incurred for each day the member engages in official board business.

(1) No compensatory per diem shall be paid to board members unless required by law, but members shall be reimbursed for travel, meals, lodging, and incidental expenses in accordance with the General Appropriations Act.

(2) A board member who is an employee of a state agency, other than the department, may not receive reimbursement for expenses from the department if he or she is reimbursed by that state agency.

(3) A nonmember of the board who is appointed to serve on a subcommittee may not receive reimbursement for expenses from the department.

(4) Each member who is to be reimbursed for expenses shall submit to staff the member's receipts for expenses and any required official forms no later than 14 days after each board meeting.

(5) Requests for reimbursement of expenses shall be made on official state travel vouchers prepared by department staff.

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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Lisa Hernandez
General Counsel
Department of State Health Services
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SUBCHAPTER D. GENERAL

25 TAC §289.205

STATUTORY AUTHORITY

The proposed amendment is authorized by Health and Safety Code, §401.051, which provides the Executive Commissioner of the Health and Human Services Commission with authority to adopt rules and guidelines relating to the control of radiation and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. The review of the rule implements Government Code, §2001.039.

The proposed amendment affects the Health and Safety Code, Chapters 401 and 1001 and Government Code, Chapter 531.

§289.205. Hearing and Enforcement Procedures.

(a) (No change.)

(b) Definitions. The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

(1) Administrative penalty--A monetary penalty assessed by the agency in accordance with the Texas Radiation Control Act

(Act), §401.384, to emphasize the need for lasting remedial action and to deter future violations.

(2) (No change.)

(3) Applicant--A person seeking a license, certificate of registration, accreditation of mammography facility, or industrial radiographer certification, issued in accordance with [~~under~~] the provisions of the Act and the requirements in this chapter.

[~~(4) Board--The Texas Board of Health.~~]

(4) [~~(5)~~] Certified industrial radiographer--An individual who meets the definition of radiographer as stated in §289.255(c) of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography).

(5) [~~(6)~~] Commissioner--The [~~Texas~~] commissioner of the Texas Department of State Health Services [~~health~~].

(6) [~~(7)~~] Contested case--A proceeding in which the agency determines the legal rights, duties, or privileges of a party after an opportunity for adjudicative hearing.

(7) [~~(8)~~] Director--The director of the radiation control program in accordance with [~~under~~] the agency's jurisdiction.

(8) [~~(9)~~] Enforcement conference--A meeting held by the agency with a person to discuss the following:

(A) safety, safeguards, or environmental problems;

(B) compliance with regulatory, license condition, or registration condition requirements;

(C) proposed corrective measures including, but not limited to, schedules for implementation; and

(D) enforcement options available to the agency.

(9) [~~(10)~~] Hearing--A proceeding to examine an application or other matter before the agency in order to adjudicate rights, duties, or privileges.

(10) [~~(11)~~] Interested person--A person who participates in a hearing concerning a contested case but who is not admitted as a party by the ALJ.

(11) [~~(12)~~] Major amendment--An amendment to a license issued in accordance with the requirements of §289.260 of this title (relating to Licensing of Uranium Recovery and Byproduct Material Disposal Facilities) that:

(A) reflects a transfer of ownership of the licensed facility;

(B) authorizes enlargement of the licensed area beyond the boundaries of the existing license;

(C) authorizes a change of the method specified in the license for disposal of byproduct material as defined in the Act, §401.003(3)(B); or

(D) grants an exemption from any provision of §289.260 of this title.

(12) [~~(13)~~] Notice of violation--A written statement prepared by the department of one or more alleged infringements of a legally binding requirement. [~~The notice requires the person receiving the notice to provide a written statement describing the following:~~]

[~~(A) corrective steps taken by the person and the results achieved;~~]

[~~(B) corrective steps to be taken to prevent recurrence; and~~]

[~~(C) the projected date for achieving full compliance. The agency may require responses to notices of violation to be under oath.~~]

(13) [~~(14)~~] Order--A specific directive contained in a legal document issued by the agency.

(14) [~~(15)~~] Party--A person designated as such by the ALJ. A party may consist of the following:

(A) the agency;

(B) an applicant, licensee, registrant, accredited mammography facility, or certified industrial radiographer; and

(C) any person affected.

(15) [~~(16)~~] Person affected--A person who demonstrates that the person has suffered or will suffer actual injury or economic damage and, if the person is not a local government, is:

(A) a resident of a county, or a county adjacent to the county, in which radioactive material is or will be located; or

(B) doing business or has a legal interest in land in the county or adjacent county.

(16) [~~(17)~~] Preliminary report--A document prepared by the agency containing the following:

(A) a statement of facts on which the agency bases the conclusion that a violation has occurred;

(B) recommendations that an administrative penalty be imposed on the person charged;

(C) recommendations for the amount of that proposed penalty; and

(D) a statement that the person charged has a right to a hearing on the occurrence of the violation, the amount of the penalty, or both.

(17) [~~(18)~~] Radiation and Perpetual Care Account--An account established for the purposes described in the Act, §401.305.

(18) [~~(19)~~] Requestor--A person claiming party status as a person affected.

(19) [~~(20)~~] Severity level--A classification of violations based on relative seriousness of each violation and the significance of the effect of the violation on the occupational or public health or safety or the environment.

(20) [~~(21)~~] Violation--An infringement of any rule, license or registration condition, order of the agency, or any provision of the Act.

(c) Procedures for licensing actions in accordance with [~~under~~] the Act, §401.054.

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

(d) - (f) (No change.)

(g) Revocation of accreditation of mammography facilities.

(1) An accreditation of a mammography facility may be revoked, for any of the following:

(A) any material false statement in the application or any statement of fact required in accordance with [~~under provision of~~] the Act;

(B) - (C) (No change.)

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

(h) (No change.)

(i) Compliance procedures for licensees, registrants, certified industrial radiographers, and other persons.

(1) A licensee, registrant, certified industrial radiographer, or other person who commits a violation(s) will be issued a notice of violation. The person receiving the notice shall provide the agency with a written statement and supporting documentation by the date stated in the notice describing the following:

(A) steps taken by the person and the results achieved;

(B) corrective steps to be taken to prevent recurrence; and

(C) the date when full compliance was or is expected to be achieved. The agency may require responses to notices of violation to be under oath.

(2) - (4) (No change.)

(5) When the agency determines that the action provided for in paragraph (8) of this subsection or subsection (j) of this section is not to be taken immediately, the agency may offer the licensee, registrant, or certified industrial radiographer an opportunity to attend an informal meeting [~~enforcement conference~~] to discuss the following with the agency:

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

(6) Notice of any informal meeting [~~enforcement conference~~] shall be delivered by personal service, or certified mail, addressed to the last known address. An informal meeting [~~enforcement conference~~] is not a prerequisite for the action to be taken in accordance with [~~under~~] paragraph (8) of this subsection or subsection (j) of this section.

(7) Except in cases in which the occupational and public health, [~~interest,~~] or safety requires otherwise, no license, certificate of registration, or industrial radiographer certification shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, facts or conduct that may warrant such action shall have been called to the attention of the licensee, registrant, or certified industrial radiographer in writing, and the licensee, registrant, or certified industrial radiographer shall have been afforded [~~accorded~~] an opportunity to demonstrate compliance with all lawful requirements.

(8) - (9) (No change.)

(j) Assessment of administrative penalties.

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

(3) Application of administrative penalties. The agency may impose differing levels of penalties for different severity level violations and different classes of users as follows.

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

(C) Adjustments to the [~~severity levels and~~] percentages of base amounts in Table IB may be made for the presence or absence of the following factors:

(i) - (vi) (No change.)

(D) The penalty for each violation may be in an amount not to exceed $10,000 a day for a person who violates the Act or a rule, order, license or registration issued in accordance with [~~under~~] the Act. Each day a violation continues may be considered a separate violation for purposes of penalty assessment.

(4) The department [~~Office of General Counsel~~] may conduct settlement negotiations.

(k) Severity levels of violations for licensees, registrants, certified industrial radiographers, or other persons.

(1) Violations for licensees, registrants, certified industrial radiographers, or other persons shall be categorized by one of the following severity levels.

(A) Severity level I are violations that are most significant and may have a significant negative impact on occupational and/or public health and safety or on the environment. Severity level I violations are most significant and may have a significant negative impact by increasing the risk of unauthorized use of radioactive material that would be detrimental to public health and safety.

(B) Severity level II are violations that are very significant and may have a negative impact on occupational and/or public health and safety or on the environment. Severity level II violations are very significant and may have a negative impact by increasing the risk of unauthorized use of radioactive material that would be detrimental to public health and safety.

(C) Severity level III are violations that are significant and which, if not corrected, could threaten occupational and/or public health and safety or the environment. Severity level III are significant and, if not corrected, could increase the risk of unauthorized use of radioactive material that would be detrimental to public health and safety.

(D) - (E) (No change.)

(2) (No change.)

(3) Criteria to elevate or reduce severity levels.

(A) Severity levels [~~Violations~~] may be elevated to a higher severity level for the following reasons:

(i) - (iii) (No change.)

(iv) a violation was willful or grossly negligent; [~~. This means the violation was the result of careless regard for requirements, deception, or other indications of willfulness by the licensee/registrant or employees of the licensee/registrant, or certified industrial radiographer; or~~]

(v) compliance history; or [~~.~~]

(vi) other mitigating factors.

(B) Severity levels [~~Violations~~] may be reduced to a lower level for the following reasons:

(i) the licensee/registrant identified and corrected the violation prior to the agency inspection; [~~or~~]

(ii) the licensee/registrant's actions corrected the violation and prevented recurrence; or [~~.~~]

(iii) other mitigating factors.

(4) (No change.)

(l) Impoundment of sources of radiation.

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

(3) If agency action is necessary to protect the public health and safety, no prior notice need be given the owner or possessor. If agency action is not necessary to protect the public health and safety, the agency will give written notice to the owner and/or the possessor of the impounded source of radiation of the intention to dispose of the source of radiation. Notice shall be the same as provided in subsection (i)(8) of this section. The owner or possessor shall have 30 days

from the date of personal service or mailing to request a hearing in accordance with [~~under~~] the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title, and in accordance with subsection (i)(9) of this section, concerning the intention of the agency. If no hearing is requested within that period of time, the agency may take the contemplated action, and such action is final.

(4) - (5) (No change.)

(m) Emergency orders.

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

(5) The agency shall use any security provided by a licensee in accordance with [~~under~~] the Act to pay toward the costs of such actions and corrective measures taken. If the cost of actions and corrective measures require more funds than the security has provided, the agency shall request the Attorney General to seek reimbursement from the licensee or person causing the threat.

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

(6) (No change.)

(n) (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 August 29, 2007.

TRD-200703962
Lisa Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 458-7111 x6972

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SUBCHAPTER F. LICENSE REGULATIONS

25 TAC §289.257

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

STATUTORY AUTHORITY

The proposed repeal is authorized by Health and Safety Code, §401.051, which provides the Executive Commissioner of the Health and Human Services Commission with authority to adopt rules and guidelines relating to the control of radiation, and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. The review of the rule implements Government Code, §2001.039.

The proposed repeal affects the Health and Safety Code, Chapters 401 and 1001, and Government Code, Chapter 531.

§289.257. Packaging and Transportation of Radioactive Material.

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 August 29, 2007.

TRD-200703963
Lisa Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 458-7111 x6972

♦ ♦ ♦

25 TAC §289.257

STATUTORY AUTHORITY

The proposed new section is authorized by Health and Safety Code, §401.051, which provides the Executive Commissioner of the Health and Human Services Commission with authority to adopt rules and guidelines relating to the control of radiation, and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. The review of the rule implements Government Code, §2001.039.

The proposed new section affects the Health and Safety Code, Chapters 401 and 1001, and Government Code, Chapter 531.

§289.257. Packaging and Transportation of Radioactive Material.

(a) Purpose.

(1) This section establishes requirements for packaging, preparation for shipment, and transportation of radioactive material including radioactive waste.

(2) The packaging and transport of radioactive material are also subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials), §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.251 of this title (relating to Exemptions, General Licenses, and General License Acknowledgements), §289.252 of this title (relating to Licensing of Radioactive Material), §289.254 of this title (relating to Licensing of Radioactive Waste Processing and Storage Facilities), §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material, and §289.260 of this title (relating to Licensing of Uranium Recovery and Byproduct Material Disposal Facilities) and to the regulations of other agencies (e.g., the United States Department of Transportation (DOT) and the United States Postal Service) having jurisdiction over means of transport. The requirements of this section are in addition to, and not in substitution for, other requirements.

(b) Scope.

(1) The requirements of this section apply to any licensee authorized by a specific or general license issued by the agency to receive, possess, use, or transfer radioactive material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the agency license, or transports that material on public highways. No provision of this section authorizes possession of radioactive material.

(2) Exemptions from the requirements for a license in subsection (c) of this section are specified in subsection (f) of this section. The general license in subsection (i) of this section requires that a United States Nuclear Regulatory Commission (NRC) certificate of compliance or other package approval be issued for the package to be used in accordance with the general license. The transport of radioactive material or delivery of radioactive material to a carrier for transport is subject to the operating controls and procedural requirements of subsections (l) - (q) of this section and to the general provisions of subsections (a) - (e) of this section, including DOT regulations referenced in subsection (e) of this section.

(c) Requirement for license. Except as authorized in a general or specific license issued by the agency, or as exempted in accordance with this section, no licensee may transport radioactive material or deliver radioactive material to a carrier for transport.

(d) Definitions. The following words and terms when used in this section shall have the following meaning, unless the context clearly indicates otherwise. To ensure compatibility with international transportation standards, all limits in this section are given in terms of dual units: The International System of Units (SI) followed or preceded by United States (U.S.) standard or customary units. The U.S. customary units are not exact equivalents, but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this section, SI units shall be used.

(1) A_1--The maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Table 257-3 of subsection (aa)(6) of this section, or may be derived in accordance with the procedure prescribed in subsection (aa) of this section.

(2) A_2--The maximum activity of radioactive material, other than special form, low specific activity (LSA) and surface contaminated object (SCO) material, permitted in a Type A package. This value is either listed in Table 257-3 of subsection (aa)(6) of this section, or may be derived in accordance with the procedure prescribed in subsection (aa) of this section.

(3) BRC Forms 540, 540A, 541, 541A, 542, and 542A--Official agency forms referenced in subsection (bb) of this section which includes the information required by DOT in Title 49, Code of Federal Regulations (CFR), Part 172. BRC Form 541B contains additional information for low-level radioactive waste (LLRW) shipments to a Texas LLRW disposal facility. Licensees need not use originals of these forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, BRC Forms 541 (and 541A and 541B) and BRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media shall have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

(4) Carrier--A person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

(5) Certificate holder--A person who has been issued a certificate of compliance or other package approval by the agency.

(6) Certificate of compliance--The certificate issued by the NRC that approves the design of a package for the transportation of radioactive materials.

(7) Chelating agent--Amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxy-carboxylic acids, and polycarboxylic acids (e.g., citric acid, carbolic acid, and glucinic acid).

(8) Chemical description--A description of the principal chemical characteristics of a LLRW.

(9) Consignee--The designated receiver of the shipment of low-level radioactive waste.

(10) Consignment--each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

(11) Containment system--The assembly of components of the packaging intended to retain the radioactive material during transport.

(12) Conveyance--For transport on:

(A) public highway or rail by transport vehicle or large freight container;

(B) water by vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

(C) aircraft.

(13) Criticality Safety Index (CSI)--The dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of the criticality safety index is described in subsection (i) of this section and Title 10, CFR, §71.59.

(14) Decontamination facility--A facility operating in accordance with an NRC, agreement state, or agency license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this section, is not considered to be a consignee for LLRW shipments.

(15) Deuterium--For the purposes of this section, this means deuterium and any deuterium compound, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

(16) Disposal container--A transport container principally used to confine LLRW during disposal operations at a land disposal facility (also see definition for high integrity container). Note that for some shipments, the disposal container may be the transport package.

(17) Environmental Protection Agency (EPA) identification number--The number received by a transporter following application to the administrator of EPA as required by Title 40, CFR, Part 263.

(18) Exclusive use--The sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier shall ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor shall issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

(19) Fissile material--The radionuclides plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only are not included in this definition. Agency jurisdiction extends only to special nuclear

material in quantities not sufficient to form a "critical mass" as defined in §289.201(b) of this title. Certain exclusions from fissile material controls are provided in subsection (h) of this section.

(20) Generator--A licensee operating in accordance with an NRC, agreement state, or agency license who:

(A) is a waste generator as defined in this section; or

(B) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

(21) Graphite--For the purposes of this section, this means graphite with a boron equivalent content of less than five parts per million and density greater than 1.5 grams per cubic centimeter.

(22) High integrity container (HIC)--A container commonly designed to meet the structural stability requirements of Title 10, CFR, §61.56, and to meet DOT requirements for a Type A package.

(23) Industrial package (IP)--A packaging that, together with its low specific activity (LSA) material or surface contaminated object (SCO) contents, meets the requirements of Title 49, CFR, §173.410 and §173.411. Industrial packages are categorized in Title 49, CFR, §173.411 as either:

(A) Industrial package Type 1 (IP-1);

(B) Industrial package Type 2 (IP-2); or

(C) Industrial package Type 3 (IP-3).

(24) Low-level radioactive waste (LLRW)--Radioactive material that meets the following criteria:

(A) LLRW is radioactive material that is:

(i) discarded or unwanted and is not exempt by rule adopted in accordance with the Texas Radiation Control Act (Act), Health and Safety Code, §401.106;

(ii) waste, as that term is defined in Title 10, CFR, §61.2; and

(iii) subject to:

(I) concentration limits established in Title 10, CFR §61.55, or compatible rules adopted by the agency or the Texas Commission on Environmental Quality (TCEQ), as applicable; and

(II) disposal criteria established in Title 10, CFR, or established by the agency or TCEQ, as applicable.

(B) LLRW does not include:

(i) high-level radioactive waste as defined in Title 10, CFR, §60.2;

(ii) spent nuclear fuel as defined in Title 10, CFR, §72.3;

(iii) byproduct material defined in the Act, Health and Safety Code, §401.003(3)(B);

(iv) naturally occurring radioactive material (NORM) waste that is not oil and gas NORM waste;

(v) oil and gas NORM waste; or

(vi) transuranics greater than 100 nanocuries per gram.

(25) Low specific activity (LSA) material--Radioactive material with limited specific activity which is nonfissile or is excepted in accordance with subsection (h) of this section, and which satisfies the following descriptions and limits set forth. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material shall be in one of the following three groups:

(A) LSA-I.

(i) Ores containing only naturally occurring radionuclides (e.g., uranium, thorium) and uranium or thorium concentrates of such ores which are not intended to be processed for the use of these radionuclides; or

(ii) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; or

(iii) Radioactive material for which the A_2 value is unlimited; or

(iv) Other radioactive material (e.g.: mill tailings, contaminated earth, concrete, rubble, other debris, and activated material) in which the radioactivity is distributed throughout, and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with subsection (aa) of this section.

(B) LSA-II.

(i) Water with tritium concentration up to 0.8 terabecquerel per liter (TBq/l) (20.0 curies per liter (Ci/l)); or

(ii) Other material in which the radioactivity is distributed throughout, and the average specific activity does not exceed 10^{-4} A_2/g for solids and gases, and 10^{-5} A_2/g for liquids.

(C) LSA-III. Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of Title 10, CFR, §71.77 in which:

(i) the radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and

(ii) the radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even with a loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, would not exceed 0.1 A_2; and

(iii) the average specific activity of the solid does not exceed 2×10^{-3} A_2/g.

(26) Low toxicity alpha emitters--Natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than ten days.

(27) Maximum normal operating pressure--The maximum gauge pressure that would develop in the containment system in a period of one year under the heat condition specified in Title 10, CFR, §71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

(28) Natural thorium--Thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

(29) Normal form radioactive material--Radioactive material that has not been demonstrated to qualify as special form radioactive material.

(30) Package--The packaging together with its radioactive contents as presented for transport.

(A) Fissile material package, Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package--A fissile material packaging together with its fissile material contents.

(B) Type A package--A Type A packaging together with its radioactive contents. A Type A package is defined and shall comply with the DOT regulations in Title 49, CFR, Part 173.

(C) Type B package--A Type B packaging together with its radioactive contents. On approval by the NRC, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kilopascals (kPa) (100 pounds per square inch (lb/in^2)) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in Title 10, CFR, §71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in Title 49, CFR, Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in Title 10, CFR, §71.19.

(31) Packaging--The assembly of components necessary to ensure compliance with the packaging requirements of this section. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

(32) Physical description--The items called for on BRC Form 541 to describe a LLRW.

(33) Residual waste--LLRW resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

(34) Shipper--The licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers LLRW for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator. This definition applies only to shipments of LLRW shipped to a Texas LLRW disposal facility.

(35) Site of usage--The licensee's facility, including all buildings and structures between which radioactive material is transported and all roadways that are not within the public domain on which radioactive material can be transported.

(36) Specific activity of a radionuclide--The radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(37) Spent nuclear fuel or spent fuel--Fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least one year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

(38) Surface contaminated object (SCO)--A solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. A SCO shall be in one of the following two groups with surface activity not exceeding the following limits:

(A) SCO-I--A solid object on which:

(i) the non-fixed contamination on the accessible surface averaged over 300 square centimeters (cm^2) (or the area of the surface if less than 300 cm^2) does not exceed 4 becquerels per square centimeter (Bq/cm^2) (10^{-4} microcurie per square centimeter (μCi/cm^2)) for beta and gamma and low toxicity alpha emitters, or 4 x 10^{-1} Bq/cm^2 (10^{-5} μCi/cm^2) for all other alpha emitters;

(ii) the fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4 x 10^4 Bq/cm^2 (1 μCi/cm^2) for beta and gamma and low toxicity alpha emitters, or 4 x 10^3 Bq/cm^2 (10^{-1} μCi/cm^2) for all other alpha emitters; and

(iii) the non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 4 x 10^4 Bq/cm^2 (1 μCi/cm^2) for beta and gamma and low toxicity alpha emitters, or 4 x 10^3 Bq/cm^2 (10^{-1} μCi/cm^2) for all other alpha emitters.

(B) SCO-II--A solid object on which the limits for SCO-I are exceeded and on which the following limits are not exceeded:

(i) the non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 400 Bq/cm^2 (10^{-2} μCi/cm^2) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm^2 (10^{-3} μCi/cm^2) for all other alpha emitters;

(ii) the fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8 x 10^5 Bq/cm^2 (20 μCi/cm^2) for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 μCi/cm^2) for all other alpha emitters; and

(iii) the non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 8 x 10^5 Bq/cm^2 (20 μCi/cm^2) for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 μCi/cm^2) for all other alpha emitters.

(39) Uniform Low-Level Radioactive Waste Manifest or uniform manifest--The combination of BRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

(40) Unirradiated uranium--Uranium containing not more than 2 x 10^3 Bq of plutonium per gram of uranium-235, not more than 9 x 10^6 Bq of fission products per gram of uranium-235, and not more than 5 x 10^{-3} g of uranium-236 per gram of uranium-235.

(41) Uranium--Natural, depleted, enriched:

(A) Natural uranium--Uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

(B) Depleted uranium--Uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(C) Enriched uranium--Uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(42) Waste collector--An entity, operating in accordance with an NRC, agreement state, or agency license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

(43) Waste description--The physical, chemical and radiological description of a LLRW as called for on BRC Form 541.

(44) Waste generator--An entity, operating in accordance with an NRC, agreement state, or agency license, who:

(A) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use; and

(B) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a waste generator if the transfer of LLRW from its facility is defined as residual waste.

(45) Waste processor--An entity, operating in accordance with an NRC or agreement state license, whose principal purpose is to process, repackage, or otherwise treat LLRW or waste generated by others prior to eventual transfer of waste to a licensed LLRW land disposal facility.

(46) Waste type--A waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically-defined media).

(e) Transportation of radioactive material.

(1) Each licensee who transports radioactive material outside the site of usage as specified in the agency license, transports on public highways, or delivers radioactive material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in Title 49, CFR, Part 107, Parts 171 - 189 and 390 - 397 appropriate to the mode of transport. The licensee shall particularly note DOT regulations in the following areas:

(A) Packaging--Title 49, CFR, Part 173: Subparts A, B, and I.

(B) Marking and labeling--Title 49, CFR, Part 172: Subpart D, and §§172.400 - 172.407 and §§172.436 - 172.441 of Subpart E.

(C) Placarding--Title 49, CFR, Part 172: Subpart F, especially §§172.500 - 172.519 and §172.556, and Appendices B and C.

(D) Accident reporting--Title 49, CFR, Part 171: §171.15 and §171.16.

(E) Shipping papers and emergency information--Title 49, CFR, Part 172: Subparts C and G.

(F) Hazardous material employee training--Title 49, CFR, Part 172: Subpart H.

(G) Hazardous material shipper/carrier registration--Title 49, CFR, Part 107: Subpart G.

(H) Security Plans--Title 49, CFR, Part 172: Subpart I.

(2) The licensee shall also note DOT regulations pertaining to the following modes of transportation:

(A) Rail: Title 49, CFR Part 174: Subparts A through D and K.

(B) Air: Title 49, CFR Part 175.

(C) Vessel: Title 49, CFR Part 176: Subparts A through F and M.

(D) Public Highway: Title 49, CFR Part 177 and Parts 390 through 397.

(3) If DOT regulations are not applicable to a shipment of radioactive material (i.e. DOT does not have jurisdiction), the licensee shall conform to DOT standards and requirements specified in paragraph (1) of this subsection to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, waiver, or exemption from those requirements shall be filed and approved by the agency. Any notification referred to in those requirements, shall be submitted to the agency.

(f) Exemption for low-level radioactive materials.

(1) A licensee is exempt from all requirements of this section with respect to shipment or carriage of the following low-level materials:

(A) Natural material and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the values specified in Table 257-4 of subsection (aa)(7) of this section.

(B) Materials for which the activity concentration is not greater than the activity concentration values specified in Table 257-4 of subsection (aa)(7) of this section, or for which the consignment activity is not greater than the limit for an exempt consignment found in Table 257-4 of subsection (aa)(7) of this section.

(2) Common and contract carriers, freight forwarders, and warehousemen, who are subject to the rules and regulations of the DOT or the United States Postal Service (Title 39, CFR, Parts 14 and 15), are exempt from these regulations to the extent that they transport or store sources of radiation in the regular course of their carriage for another or storage incident thereto. Private carriers who are subject to the rules and regulations of the DOT are exempted from these regulations to the extent that they transport sources of radiation. Common, contract, and private carriers who are not subject to the rules and regulations of the DOT or the United States Postal Service are subject to applicable sections of these regulations.

(3) Persons who discard licensed material in accordance with §289.202(fff) of this title are exempt from all requirements of this section.

(g) Exemption of physicians. Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from Title 10, CFR, §71.5 with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under this exemption shall be licensed under Title 10, CFR, Part 35 or the equivalent agreement state regulations.

(h) Exemption from classification as fissile material. Fissile materials meeting the requirements of at least one of the paragraphs (1) through (6) of this subsection are exempt from classification as fissile material and from the fissile material package standards of Title 10, CFR §71.55 and §71.59, but are subject to all other requirements of this section, except as noted.

(1) An individual package containing 2 grams or less fissile material.

(2) Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but shall not be included in determining the required mass for solid nonfissile material.

(3) Solid fissile material commingled with solid non-fissile material.

(A) Low concentrations of solid fissile material commingled with solid nonfissile material provided:

(i) that there is at least 2000 grams of solid nonfissile material for every gram of fissile material, and

(ii) there is no more than 180 grams of fissile material distributed within 360 kg of contiguous non-fissile material.

(B) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but shall not be included in determining the required mass of solid nonfissile material.

(4) Uranium enriched in uranium-235 to a maximum of 1% by weight, and with total plutonium and uranium-233 content of up to 1% of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5 percent of the uranium mass.

(5) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2 percent by mass, with a total plutonium and uranium-233 content not exceeding 0.002 percent of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material shall be contained in at least a DOT Type A package.

(6) Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20 percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

(i) General license.

(1) NRC-approved package.

(A) A general license is issued to any licensee of the agency to transport, or to deliver to a carrier for transport, radioactive material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC.

(B) This general license applies only to a licensee who has a quality assurance program approved by the NRC as satisfying the provisions of Title 10, CFR, Part 71, Subpart H.

(C) This general license applies only to a licensee who meets the following requirements:

(i) has a copy of the CoC or other approval by the NRC of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

(ii) complies with the terms and conditions of the specific license, certificate, or other approval by the NRC, as applicable, and the applicable requirements of Title 10, CFR, Part 71, Subparts A, G, and H; and

(iii) Before the licensee's first use of the package, submits in writing to: ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in Title 10, CFR, Part 71, the licensee's name and license number and the package identification number specified in the package approval.

(D) This general license applies only when the package approval authorizes use of the package in accordance with this general license.

(E) For a Type B or fissile material package, the design of which was approved by NRC before April 1, 1996, the general license is subject to the additional restrictions of paragraph (2) of this subsection.

(F) For radiography containers, a program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of §289.255(m)(2)(B) of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography), is deemed to satisfy the requirements of subparagraph (B) of this paragraph.

(2) Previously approved package.

(A) A Type B package previously approved by the NRC, but not designated as B(U), B(M), B(U)F or B(M)F in the identification number of the NRC certificate of compliance, or Type AF packages approved by the NRC prior to September 6, 1983, may be used in accordance with the general license of paragraph (1) of this subsection with the following additional conditions:

(i) fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with subsection (k)(3) of this section;

(ii) a serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging ; and

(iii) subparagraph (A) of this paragraph expires October 1, 2008.

(B) A Type B(U) package, a Type B(M) package, or a fissile material package, previously approved by the NRC but without the designation "-85" in the identification number of the NRC CoC, may be used in accordance with the general license of paragraph (1) of this subsection with the following additional conditions:

(i) fabrication of the package is satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with subsection (k)(3) of this section;

(ii) a package used for a shipment to a location outside the United States is subject to multilateral approval as defined in DOT regulations Title 49, CFR §173.403; and

(iii) a serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

(C) A Type B(U) package, a Type B(M) package, or a fissile material package, previously approved by the NRC with the designation "-85" in the identification number of the NRC CoC, may be used in accordance with the general license of paragraph (1) of this subsection with the following additional conditions:

(i) Fabrication of the package shall be satisfactorily completed by December 31, 2006, as demonstrated by application of its model number in accordance with subsection (k)(3) of this section.

(ii) After December 31, 2003, a package used for a shipment to a location outside the United States is subject to multilateral approval as defined in DOT regulations Title 49, CFR, §173.403.

(3) DOT specification container.

(A) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in Title 49, CFR, Parts 173 and 178.

(B) This general license applies only to a licensee who:

(i) has a quality assurance program required by subsections (t), (u), and (v) of this section and Title 10, CFR, Part 71, Subpart H;

(ii) has a copy of the specification; and

(iii) complies with the terms and conditions of the specification and the applicable requirements of this section.

(C) The general license in subparagraph (A) of this paragraph is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in Title 49, CFR, §173.403.

(4) Use of foreign approved package

(A) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate that has been revalidated by the DOT as meeting the applicable requirements of Title 49, CFR, §171.12.

(B) Except as otherwise provided by this section, the general license applies only to a licensee who has a quality assurance program approved by the NRC as satisfying the applicable provisions of Title 10, CFR, Part 71.

(C) This general license applies only to international shipments.

(D) This general license applies only to a licensee who:

(i) has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment; and

(ii) complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of this section. With respect to the quality assurance provisions of Title 10, CFR, Part 71, the licensee is exempt from design, construction, and fabrication considerations.

(5) Fissile material.

(A) A general license is issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package that meets the standards of this section; however, the material shall be contained in a Type A package. The Type A package shall also meet the DOT requirements of Title 49, CFR, §173.417(a).

(B) The general license applies only to a licensee who has a quality assurance program approved by the NRC as satisfying the provisions of Title 10, CFR, Part 71.

(C) The general license applies only when a package's contents:

(i) contain no more than a Type A quantity of radioactive material; and

(ii) contain less than 500 total grams of beryllium, graphite, or hydrogeneous material enriched in deuterium.

(D) The general license applies only to packages containing fissile material that are labeled with a CSI that:

(i) has been determined in accordance with paragraph (E) of this subsection;

(ii) has a value less than or equal to 10.0; and

(iii) for a shipment of multiple packages containing fissile material, the sum of the CSIs shall be less than or equal to 50.0 (for shipment on a nonexclusive use conveyance) and less than or equal to 100.0 (for shipment on an exclusive use conveyance).

(E) The CSI shall be as follows:

(i) the value for the CSI shall be greater than or equal to the number calculated by the following equation:
Figure: 25 TAC §289.257(i)(5)(E)(i)

(ii) the calculated CSI shall be rounded up to the first decimal place;

(iii) the values of X, Y, and Z used in the CSI equation shall be taken from Tables 257-1 or 257-2 of this clause, as appropriate;
Figure: 25 TAC §289.257(i)(5)(E)(iii)

(iv) if Table 257-2 of clause (iii) of this subparagraph is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium shall be assumed to be zero; and

(v) Table 257-2 values of clause (iii) of this subparagraph for X, Y, and Z shall be used to determine the CSI if:

(I) uranium-233 is present in the package;

(II) the mass of plutonium exceeds 1% of the mass of uranium-235;

(III) the uranium is of unknown uranium-235 enrichment, or greater than 24 weight percent enrichment; or

(IV) substances having a moderating effectiveness (i.e. an average hydrogen density greater than H_2O) (e.g. certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

(6) Plutonium-beryllium special form material.

(A) A general license is issued to any licensee to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section. This material need not be contained in a package that meets the standards of Title 10, CFR, Part 71, however, the material shall be contained in a Type A package. The Type A package shall also meet the DOT requirements of Title 49, CFR, §173.417(a).

(B) The general license applies only to a licensee who has a quality assurance program approved by the NRC as satisfying the provisions of Title 10, CFR, Part 71.

(C) The general license applies only when a package's contents:

(i) contain no more than a Type A quantity of material; and

(ii) contain less than 1000g of plutonium, provided that plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 g of the total quantity of plutonium in the package.

(D) The general license applies only to packages labeled with a CSI that:

(i) has been determined in accordance with subparagraph (E) of this paragraph;

(ii) has a value less than or equal to 100.0; and

(iii) for a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs shall be less than or equal to 50.0 (for shipment on a nonexclusive use conveyance) and less than or equal to 100.0 (for shipment on or exclusive use conveyance).

(E) The value for the CSI shall be as follows:

(i) the CSI shall be greater than or equal to the number calculated by the following equation:
Figure: 25 TAC §289.257(i)(6)(E)(i)

(ii) the calculated CSI shall be rounded up to the first decimal place.

(j) Assumptions as to unknown properties. When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

(k) Preliminary determinations. Before the first use of any packaging for the shipment of licensed material the licensee shall:

(1) ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging;

(2) where the maximum normal operating pressure will exceed 35 kPa (5 lb/in^2) gauge, test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure; and

(3) conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by NRC. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the NRC.

(l) Routine determinations. Before each shipment of radioactive material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this section and of the license. The licensee shall determine that:

(1) the package is proper for the contents to be shipped;

(2) the package is in unimpaired physical condition except for superficial defects such as marks or dents;

(3) each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;

(4) any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(5) any pressure relief device is operable and set in accordance with written procedures;

(6) the package has been loaded and closed in accordance with written procedures;

(7) for fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(8) any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose, unless it satisfies the design requirements of Title 10, CFR, §71.45;

(9) the level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable (ALARA), and within the limits specified in DOT regulations in Title 49, CFR, §173.443;

(10) external radiation levels around the package and around the vehicle, if applicable, will not exceed the following limits at any time during transportation:

(A) Except as provided in subparagraph (B) of this paragraph, each package of radioactive materials offered for transportation shall be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/hr (200 mrem/hr) at any point on the external surface of the package, and the transport index does not exceed 10.

(B) A package that exceeds the radiation level limits specified in subparagraph (A) of this paragraph shall be transported by exclusive use shipment only, and the radiation levels for such shipment shall not exceed the following during transportation:

(i) 2 mSv/hr (200 mrem/hr) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/hr (1,000 mrem/hr):

(I) the shipment is made in a closed transport vehicle;

(II) the package is secured within the vehicle so that its position remains fixed during transportation; and

(III) there are no loading or unloading operations between the beginning and end of the transportation;

(ii) 2 mSv/hr (200 mrem/hr) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and

(iii) 0.1 mSv/hr (10 mrem/hr) at any point 2 meters (m) (6.6 feet (ft)) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point 2 m (6.6 ft) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

(iv) 0.02 mSv/hr (2 mrem/hr) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with §289.202(q) of this title;

(C) For shipments made in accordance with the provisions of subparagraph (B) of this paragraph, the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions shall be included with the shipping paper information.

(D) The written instructions required for exclusive use shipments shall be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public.

(11) a package shall be designed, constructed, and prepared for transport so that in still air at 38 degrees Celsius (100 degrees Fahrenheit) and in the shade, no accessible surface of a package would have a temperature exceeding 50 degrees Celsius (122 degrees Fahrenheit) in a nonexclusive use shipment, or 85 degrees Celsius (185 degrees Fahrenheit) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.

(m) Air transport of plutonium.

(1) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this section or included indirectly by citation of Title 49, CFR, Chapter I, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

(A) the plutonium is contained in a medical device designed for individual human application; or

(B) the plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Table 257-4 of subsection (aa)(7) of this section, and in which the radioactivity is essentially uniformly distributed; or

(C) the plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form, and is shipped in accordance with subsection (e) of this section; or

(D) the plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the NRC.

(2) Nothing in paragraph (1) of this subsection is to be interpreted as removing or diminishing the requirements of Title 10, CFR, §73.24.

(3) For a shipment of plutonium by air which is subject to paragraph (1) of this subsection, the licensee shall, through special arrangement with the carrier, require compliance with Title 49, CFR, §175.704, DOT regulations applicable to the air transport of plutonium.

(n) Opening instructions. Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with §289.202(ee)(5) of this title.

(o) Records. For a period of three years after shipment, each licensee shall maintain, for inspection by the agency, a record of each shipment of radioactive material showing the following where applicable:

(1) identification of the packaging by model number and serial number;

(2) verification that there are no significant defects in the packaging, as shipped;

(3) type and quantity of radioactive material in each package, and the total quantity of each shipment;

(4) date of the shipment;

(5) for fissile packages and for Type B packages, any special controls exercised;

(6) name and address of the transferee;

(7) address to which the shipment was made; and

(8) surveys performed to determine compliance with subsection (l)(9) and (10) of this section.

(p) Reports. The shipper shall immediately report by telephone, telegram, mailgram, or facsimile, all radioactive waste transportation accidents to the agency and the local emergency planning committees in the county where the radioactive waste accident occurs. All other accidents involving radioactive material shall be reported in accordance with §289.202(xx) and (yy) of this title.

(q) Advance notification of transport of irradiated reactor fuel and certain radioactive waste

(1) As specified in paragraphs (2) - (4) of this subsection, each licensee shall provide advance notification to the governor of a state, or the governor's designee, of the shipment of radioactive waste, through, or across the boundary of the state, before the transport, or delivery to a carrier, for transport, of radioactive waste outside the confines of the licensee's facility or other place of use or storage.

(2) Advance notification is required in accordance with this section for shipment of irradiated reactor fuel in quantities less than that subject to advance notification requirements of Title 10, CFR, §73.37. Advanced notification is also required under this subsection for shipments of radioactive material, other than irradiated fuel, meeting the following three conditions:

(A) the radioactive waste is required by this section to be in Type B packaging for transportation;

(B) the radioactive waste is being transported to or across a state boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

(C) the quantity of radioactive waste in a single package exceeds the least of the following:

(i) 3000 times the A_1 value of the radionuclides as specified in subsection (aa) of this section for special form radioactive material;

(ii) 3000 times the A_2 value of the radionuclides as specified in subsection (aa) of this section for normal form radioactive material; or

(iii) 1000 terabecquerels (TBq) (27,000 curies (Ci)).

(3) The following are procedures for submitting advance notification:

(A) The notification shall be made in writing to the office of each appropriate governor or governor's designee and to the agency.

(B) A notification delivered by mail shall be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(C) A notification delivered by any other means than mail shall reach the office of the governor or of the governor's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(i) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of radioactive waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

(ii) The list will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

(iii) A list of the names and mailing addresses of the governors' designees is available on request from the Director, Of-

fice of State Programs, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

(D) The licensee shall retain a copy of the notification as a record for three years.

(4) Each advance notification of shipment of irradiated reactor fuel or radioactive waste shall contain the following information:

(A) the name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or radioactive waste shipment;

(B) a description of the irradiated reactor fuel or radioactive waste contained in the shipment, as specified in the regulations of DOT in Title 49, CFR, §172.202 and §172.203(d);

(C) the point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

(D) the seven-day period during which arrival of the shipment at state boundaries is estimated to occur;

(E) the destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

(F) a point of contact, with a telephone number, for current shipment information.

(5) A licensee who finds that schedule information previously furnished to a governor or governor's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the state or of the governor's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for three years.

(6) The following are procedures for a cancellation notice.

(A) Each licensee who cancels an irradiated reactor fuel or radioactive waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each state or to the governor's designee previously notified, and to the agency.

(B) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for three years.

(r) Emergency plan. Each shipper and transporter of radioactive waste shall adopt an emergency plan approved by the agency for responding to transportation accidents.

(s) Inspections. Each shipment of LLRW to a licensed land disposal facility in Texas shall be inspected by the agency prior to shipment. The waste shipper shall notify the agency no less than 72 hours prior to the scheduled shipment of the intent to transport waste to the licensed land disposal facility.

(t) Quality assurance requirements.

(1) Purpose. This subsection describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety.

(A) Quality Assurance comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service.

(B) Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

(C) The license, certificate holder, and applicant for a CoC are responsible for the following:

(i) the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging; and

(ii) the quality assurance provision which applies to its use of a packaging for the shipment of licensed material subject to this subpart.

(2) Establishment of program. Each licensee, certificate holder, and applicant for a CoC shall:

(A) Establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of this subsection, subsections (t) and (u) of this section and Title 10, CFR, §§71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging; and

(B) Execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(3) Approval of program. Before the use of any package for the shipment of licensed material subject to this subsection, each licensee shall:

(A) obtain agency approval of its quality assurance program; and

(B) file a description of its quality assurance program, including a discussion of which requirements of this subsection and subsections (u) and (v) are applicable and how they will be satisfied.

(4) Radiography containers. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of §289.255(m) of this title, is deemed to satisfy the requirements of subsection (i)(B) of this section and paragraph (2) of this subsection.

(u) Quality assurance organization. The licensee, certificate holder, and applicant for a CoC shall:

(1) be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program; and

(2) clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to safety. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(3) establish quality assurance functions as follows:

(A) assuring that an appropriate quality assurance program is established and effectively executed; and

(B) verifying , by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

(4) assure that persons and organizations performing quality assurance functions have sufficient authority and organizational freedom to:

(A) identify quality problems;

(B) initiate, recommend, or provide solutions; and

(C) verify implementation of solutions.

(v) Quality assurance program. A quality assurance program shall be maintained as follows:

(1) The licensee, certificate holder, and applicant for a CoC shall:

(A) establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of this section and Title 10, CFR, §§71.01 through 71.137;

(B) document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used; and

(C) identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(2) The licensee, certificate holder, and applicant for a CoC, through its quality assurance program, shall:

(A) provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material;

(B) assure that activities affecting quality are accomplished under suitable controlled conditions which include:

(i) the use of appropriate equipment;

(ii) suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and

(iii) all prerequisites for the given activity have been satisfied; and

(C) take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(3) The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components.

(A) The impact of malfunction or failure of the item to safety;

(B) The design and fabrication complexity or uniqueness of the item;

(C) The need for special controls and surveillance over processes and equipment;

(D) The degree to which functional compliance can be demonstrated by inspection or test; and

(E) The quality history and degree of standardization of the item.

(4) The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained.

(5) The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

(w) Quality control program. Each shipper shall adopt a quality control program to include verification of the following to ensure that shipping containers are suitable for shipments to a licensed disposal facility:

(1) identification of appropriate container(s);

(2) container testing documentation is adequate;

(3) appropriate container used;

(4) container packaged appropriately;

(5) container labeled appropriately;

(6) manifest filled out appropriately; and

(7) documentation maintained of each step.

(x) Audits. The licensee, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits, to verify compliance with all aspects of the quality assurance program, and to determine the effectiveness of the program. The audit program shall include:

(1) performance in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the area being audited;

(2) documented results that are reviewed by management having responsibility in the area audited; and

(3) follow-up action, including reaudit of deficient areas, shall be taken where indicated.

(y) Transfer for disposal and manifests.

(1) The requirements of this section and subsection (bb) of this section are designed to:

(A) control transfers of LLRW by any waste generator, waste collector, or waste processor licensee, as defined in this section, who ships LLRW either directly, or indirectly through a waste collector or waste processor, to a licensed LLRW land disposal facility, as defined in §289.201(b) of this title;

(B) establish a manifest tracking system; and

(C) supplement existing requirements concerning transfers and recordkeeping for those wastes.

(2) Beginning March 1, 1998, all affected licensees shall use subsection (bb) of this section.

(3) Each shipment of LLRW intended for disposal at a licensed land disposal facility shall be accompanied by a shipment manifest in accordance with subsection (bb)(1) of this section.

(4) Any licensee shipping LLRW intended for ultimate disposal at a licensed land disposal facility shall document the information required on the uniform manifest and transfer this recorded manifest information to the intended consignee in accordance with subsection (bb) of this section.

(5) Each shipment manifest shall include a certification by the waste generator as specified in subsection (bb)(10) of this section, as appropriate.

(6) Each person involved in the transfer for disposal and disposal of LLRW, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in subsection (bb) of this section, as appropriate.

(7) Any licensee shipping LLRW to a licensed Texas LLRW disposal facility shall comply with the waste acceptance criteria in 30 Texas Administrative Code (TAC) Part 1, Chapter 336.

(z) Fees.

(1) Each shipper shall be assessed a fee for shipments of LLRW originating in Texas or originating out-of-state being shipped to a licensed Texas LLRW disposal facility and these fees shall be:

(A) $10 per cubic foot of shipped LLRW;

(B) collected by the compact waste disposal facility and remitted to the TCEQ and deposited to the credit of the radiation and perpetual care account; and

(C) used exclusively by the agency for emergency planning for and response to transportation accidents involving LLRW.

(2) Fee assessments in accordance with this section shall be suspended when the amount of fees collected reaches $500,000, except that if the balance of fees collected is reduced to $350,000 or less, the assessments shall be reinstituted to bring the balance of fees collected to $500,000.

(3) Money expended from the radiation and perpetual care account to respond to accidents involving LLRW shall be reimbursed to the radiation and perpetual care account by the responsible shipper or transporter according to rules adopted by the board.

(aa) Appendices for determination of A_1 and A_2.

(1) Values of A_1 and A_2. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these rules are given in Table 257-3 of paragraph (6) of this subsection. The curie (Ci) values specified are obtained by converting from the terabecquerel (TBq) figure. The Terabecquerel values are the regulatory standard. The curie values are for information only and are not intended to be the regulatory standard. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

(2) Values of radionuclides not listed.

(A) For individual radionuclides whose identities are known, but are not listed in Table 257-3 of paragraph (6) of this subsection, the A_1 and A_2 values contained in Table 257-5 of paragraph (8) of this subsection may be used. Otherwise, the licensee shall obtain prior NRC approval of the A_1 and A_2 values for radionuclides not listed in Table 257-3 of paragraph (6) of this subsection, before shipping the material.

(B) For individual radionuclides whose identities are known, but that are not listed in Table 257-4 of paragraph (7) of this subsection, the exempt material activity concentration and exempt consignment activity values contained in Table 257-5 of paragraph (8) of this subsection may be used. Otherwise, the licensee shall obtain prior approval of the exempt material activity concentration and exempt consignment activity values, for radionuclides not listed in Table 257-3 of paragraph (6) of this subsection, before shipping the material.

(C) The licensee shall submit requests for prior approval, described in subparagraphs (A) and (B) of this paragraph to the agency.

(3) Calculations of A_1 and A_2 for a radionuclide not in Table 257-3 of paragraph (6) of this subsection. In the calculations of A_1 and A_2 for a radionuclide not in Table 257-3 of paragraph (6) of this subsection, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter radionuclide has a half-life either longer than ten days, or longer than that of the parent radionuclide, shall be considered as a single radionuclide, and the activity to be taken into account and the A_1 or A_2 value to be applied shall be those corresponding to the parent radionuclide of that chain. In the case of radioactive decay chains in which any daughter radionuclide has a half-life either longer than ten days, or greater than that of the parent radionuclide, the parent and those daughter radionuclides shall be considered as mixtures of different radionuclides.

(4) Determination for mixtures of radionuclides whose identities and respective activities are known. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply.

(A) For special form radioactive material, the maximum quantity transported in a Type A package is as follows:
Figure: 25 TAC §289.257(aa)(4)(A)

(B) For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:
Figure: 25 TAC §289.257(aa)(4)(B)

(C) Alternatively, an A_1 value for mixtures of special form material may be determined as follows:
Figure: 25 TAC §289.257(aa)(4)(C)

(D) An A_2 value for mixtures of normal form material may be determined as follows:
Figure: 25 TAC §289.257(aa)(4)(D)

(E) The exempt activity concentration for mixtures of nuclides may be determined as follows:
Figure: 25 TAC §289.257(aa)(4)(E)

(F) The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:
Figure: 25 TAC §289.257(aa)(4)(F)

(5) Determination when activities of some of the radionuclides are not known. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph (4) of this subsection. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

(6) A_1 and A_2 values for radionuclides. The following Table 257-3 contains A_1 an A_2 values for radionuclides:
Figure: 25 TAC §289.257(aa)(6)

(7) Exempt material activity concentrations and exempt consignment activity limits for radionuclides. The following Table 257-4 contains exempt material activity concentrations and exempt consignment activity limits for radionuclides:
Figure: 25 TAC §289.257(aa)(7)

(8) General values for A_1 and A_2. The following Table 257-5 contains general values for A_1 and A_2:
Figure: 25 TAC §289.257(aa)(8)

(9) Activity-mass relationships for uranium. The following Table 257-6 contains activity-mass relationships for uranium:
Figure: 25 TAC §289.257(aa)(9)

(bb) Appendices for the requirements for transfers of LLRW intended for disposal at licensed land disposal facilities and manifests.

(1) Manifest. A waste generator, collector, or processor who transports, or offers for transportation, LLRW intended for ultimate disposal at a licensed LLRW land disposal facility shall prepare a manifest reflecting information requested on applicable BRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable BRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)) or their equivalent. BRC Forms 540 and 540A shall be completed and shall physically accompany the pertinent LLRW shipment. Upon agreement between shipper and consignee, BRC Forms 541, 541A and 541B, and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by the agency to comply with the manifesting requirements of this section when they ship:

(A) LLRW for processing and expect its return (i.e., for storage in accordance with their license) prior to disposal at a licensed land disposal facility;

(B) LLRW that is being returned to the licensee who is the waste generator or generator, as defined in this section; or

(C) radioactively contaminated material to a waste processor that becomes the processor's residual waste.

(2) Form instructions. For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this subsection may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

(3) Forms. BRC Forms 540, 540A, 541, 541A, 541B, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained from the agency.

(4) Information requirements of the DOT. This subsection includes information requirements of the DOT, as codified in Title 49, CFR, Part 172. Information on hazardous, medical, or other waste, required to meet EPA regulations, as codified in Title 40, CFR, Parts 259 and 261 or elsewhere, is not addressed in this section, and shall be provided on the required EPA forms. However, the required EPA forms shall accompany the uniform manifest required by this section.

(5) General information. The shipper of the LLRW, shall provide the following information on the uniform manifest:

(A) the name, facility address, and telephone number of the licensee shipping the waste;

(B) an explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

(C) the name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

(6) Shipment information. The shipper of the LLRW shall provide the following information regarding the waste shipment on the uniform manifest:

(A) the date of the waste shipment;

(B) the total number of packages/disposal containers;

(C) the total disposal volume and disposal weight in the shipment;

(D) the total radionuclide activity in the shipment;

(E) the activity of each of the radionuclides hydrogren-3, carbon-14, technetium-99, iodine-129, radium-226 contained in the shipment; and

(F) the total masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

(7) Disposal container and waste information. The shipper of the LLRW shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

(A) an alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

(B) a physical description of the disposal container, including the manufacturer and model of any high integrity container;

(C) the volume displaced by the disposal container;

(D) the gross weight of the disposal container, including the waste;

(E) for waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

(F) a physical and chemical description of the waste;

(G) the total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(H) the approximate volume of waste within a container;

(I) the sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

(J) the identities and activities of individual radionuclides contained in each container, the masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

(K) the total radioactivity within each container; and

(L) for wastes consigned to a disposal facility, the classification of the waste in accordance with §289.202(ggg)(4)(A) of this title. Waste not meeting the structural stability requirements of §289.202(ggg)(4)(B)(ii) of this title shall be identified.

(8) Uncontainerized waste information. The shipper of the LLRW shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

(A) the approximate volume and weight of the waste;

(B) a physical and chemical description of the waste;

(C) the total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;

(D) for waste consigned to a disposal facility, the classification of the waste in accordance with §289.202(ggg)(4)(A) of this title. Waste not meeting the structural stability requirements of §289.202(ggg)(4)(B)(ii) of this title shall be identified;

(E) the identities and activities of individual radionuclides contained in the waste, the masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

(F) for wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

(9) Multi-generator disposal container information. This paragraph applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLRW resulting from a processor's activities may be attributable to one or more generators (including waste generators) as defined in this section). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

(A) For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

(B) For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

(i) the volume of waste within the disposal container;

(ii) a physical and chemical description of the waste, including the solidification agent, if any;

(iii) the total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(iv) the sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in §289.202(ggg)(4)(B)(ii) of this title; and

(v) radionuclide identities and activities contained in the waste, the masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

(10) Certification. An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the DOT and the agency. A collector in signing the certification is certifying that nothing has been done to the collected waste that would invalidate the waste generator's certification.

(11) Control and tracking.

(A) Any licensee who transfers LLRW to a land disposal facility or a licensed waste collector shall comply with the requirements in clauses (i) - (ix) of this subparagraph. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of clauses (iv) - (ix) of this subparagraph. A licensee shall:

(i) prepare all wastes so that the waste is classified according to §289.202(ggg)(4)(A) of this title and meets the waste characteristic requirements in §289.202(ggg)(4)(B) of this title;

(ii) label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, in accordance with §289.202(ggg)(4)(A) of this title;

(iii) conduct a quality assurance program to assure compliance with §289.202(ggg)(4)(A) and (B) of this title;

(iv) prepare the uniform manifest as required by this subsection;

(v) forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:

(I) receipt of the manifest precedes the LLRW shipment; or

(II) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both subclauses (I) and (II) of this clause are also acceptable;

(vi) include the uniform manifest with the shipment regardless of the option chosen in clause (v) of this clause;

(vii) receive acknowledgement of the receipt of the shipment in the form of a signed copy of the uniform manifest;

(viii) retain a copy of or electronically store the uniform manifest and documentation of acknowledgement of receipt as the record of transfer of radioactive material as required by §289.251 of this title, §289.252 of this title, and §289.254 of this title; and

(ix) for any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this subsection, conduct an investigation in accordance with subparagraph (D) of this paragraph.

(B) Any waste collector licensee who handles only prepackaged waste shall:

(i) acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of the uniform manifest;

(ii) prepare a new uniform manifest to reflect consolidated shipments that meet the requirements of this subsection. The waste collector shall ensure that, for each container of waste in the shipment, the uniform manifest identifies the generator of that container of waste;

(iii) forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:

(I) receipt of the uniform manifest precedes the LLRW shipment; or

(II) the uniform manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both subclauses (I) and (II) of this clause are also acceptable;

(iv) include the uniform manifest with the shipment regardless of the option chosen in clause (iii) of this subparagraph;

(v) receive acknowledgement of the receipt of the shipment in the form of a signed copy of the uniform manifest;

(vi) retain a copy of or electronically store the uniform manifest and documentation of acknowledgement of receipt as the record of transfer of radioactive material as required by §289.251 of this title, §289.252 of this title, and §289.254 of this title;

(vii) for any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in accordance with this clause, conduct an investigation in accordance with subparagraph (D) of this paragraph; and

(viii) notify the shipper and the agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance uniform manifest, unless notified by the shipper that the shipment has been cancelled.

(C) Any licensed waste processor who treats or repackages waste shall:

(i) acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of the uniform manifest;

(ii) prepare a new uniform manifest that meets the requirements of this subsection. Preparation of the new uniform manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in clause (i) of this subparagraph;

(iii) prepare all wastes so that the waste is classified according to §289.202(ggg)(4)(A) of this title and meets the waste characteristics requirements in §289.202(ggg)(4)(B) of this title;

(iv) label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with §289.202(ggg)(4)(A) and (C) of this title;

(v) conduct a quality assurance program to assure compliance with §289.202(ggg)(4)(A) and (B) of this title;

(vi) forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:

(I) receipt of the uniform manifest precedes the LLRW shipment; or

(II) the uniform manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both subclause (I) of this clause and this subclause is also acceptable;

(vii) include the uniform manifest with the shipment regardless of the option chosen in clause (vi) of this subparagraph;

(viii) receive acknowledgement of the receipt of the shipment in the form of a signed copy of the uniform manifest;

(ix) retain a copy of or electronically store the uniform manifest and documentation of acknowledgement of receipt as the record of transfer of radioactive material as required by §289.251 of this title, §289.252 of this title, and §289.254 of this title;

(x) for any shipment or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in accordance with this clause, conduct an investigation in accordance with clause (v) of this subparagraph; and

(xi) notify the shipper and the agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance uniform manifest, unless notified by the shipper that the shipment has been cancelled.

(D) Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in accordance with this section shall undergo the following:

(i) be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

(ii) be traced and reported. The investigation shall include tracing the shipment and filing a report with the agency. Each licensee who conducts a trace investigation shall file a written report with the agency within two weeks of completion of the investigation.

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 August 29, 2007.

TRD-200703964
Lisa Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 458-7111 x6972

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TITLE 28. INSURANCE

PART 1. TEXAS DEPARTMENT OF INSURANCE

CHAPTER 19. AGENTS' LICENSING
SUBCHAPTER I. LICENSING FEES

28 TAC §19.803

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

The Texas Department of Insurance proposes the repeal of §19.803, concerning license renewal fees for agents, adjusters, and other licensees. The proposed repeal is necessary to eliminate existing §19.803. That section was necessary to provide for the continuation of certain renewal fees until new fees became effective on November 1, 2002. As stated in §19.803(a), the fee structure in §19.802 applies to all licenses renewed on or after November 1, 2002. Therefore, §19.1803 has no further continuing application and, as such, is unnecessary and obsolete. Simultaneously but unrelated to this proposed repeal, the Department is also proposing amendments to §§19.801, 19.802, and 19.1002, to implement SB 1263, 80th Legislature, Regular Session, effective September 1, 2007, relating to regulation and licensing of certain insurance agents. Although both proposals concern Chapter 19, Subchapter I of this title (relating to Licensing Fees), this proposal is not affected by the proposed amendments, which were published in the September 7, 2007, issue of the *Texas Register*.

Matt Ray, Deputy Commissioner, Licensing Division, has determined that during the first five years that the proposed repeal is in effect, there will be no fiscal impact on state or local government. There will be no measurable effect on local employment or the local economy as a result of the proposal.

Mr. Ray has determined that for each year of the first five years the proposed repeal is in effect, the anticipated public benefit will be the removal of obsolete and potentially confusing provisions from the Texas Administrative Code. There is no anticipated economic cost to persons who are required to comply with the proposed repeal. There is no anticipated difference in cost of

compliance between small or micro businesses and large businesses.

The Department has determined that no private real property interests are affected by this proposal and that this proposal does not restrict or limit an owner's right to property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking or require a takings impact assessment under the Government Code §2007.043.

To be considered, written comments on the proposal must be submitted no later than 5:00 p.m. on October 8, 2007 to Gene C. Jarmon, General Counsel and Chief Clerk, Mail Code 113-2A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104. An additional copy of the comment must be simultaneously submitted to Matt Ray, Deputy Commissioner, Licensing Division, Mail Code 107-1A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104. Any request for a public hearing should be submitted separately to the Office of the Chief Clerk before the close of the public comment period. If a hearing is held, written and oral comments presented at the hearing will be considered.

The repeal is proposed under Insurance Code §§4001.005, 4001.006, 4003.004, and 36.001. Section 4001.005 authorizes the Commissioner to adopt rules necessary to implement Insurance Code, Title 13. Section 4001.006 authorizes the Department to set and collect a nonrefundable license fees from agents licensed under the Insurance Code. Section 4003.004(a) authorizes the Department to set license renewal fees. Section 36.001 provides that the Commissioner of Insurance may adopt any rules necessary and appropriate to implement the powers and duties of the Texas Department of Insurance under the Insurance Code and other laws of the state.

The following statutes are affected by the proposal: Insurance Code §§4001.005, 4001.006, and 4003.004

§19.803. License Renewal Fees.

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 August 28, 2007.

TRD-200703952
Brenda Caldwell
Assistant General Counsel
Texas Department of Insurance
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 463-6327

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TITLE 34. PUBLIC FINANCE

PART 1. COMPTROLLER OF PUBLIC ACCOUNTS

CHAPTER 3. TAX ADMINISTRATION

SUBCHAPTER V. FRANCHISE TAX

34 TAC §3.581

The Comptroller of Public Accounts (Comptroller) proposes new §3.581, concerning Margin: Taxable and Nontaxable Entities. This proposed new section implements House Bill 3, 79th Legislature, Third Called Session, 2006 and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This new section establishes guidelines to determine the taxability of legal entities under Tax Code, Chapter 171. Subsection (a) provides that this new section only applies to franchise tax reports due on or after January 1, 2008. Subsection (b) defines words and terms used in this section. Subsection (c) provides a detailed list of entities that are taxable. Subsection (d) provides a detailed list of entities that are not taxable. Subsection (e) clarifies the taxability of a single member limited liability company.

John Heleman, Chief Revenue Estimator, has determined that, for the first five-year period the proposed new rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that, for each year of the first five years the proposed new rule is in effect, the public benefit anticipated as a result of enforcing the rule will be in providing guidance to businesses operating in Texas regarding their taxability status under Tax Code, Chapter 171. This new rule is proposed under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed new rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

This new section is proposed under Tax Code, §111.002 and §111.022, which provides the Comptroller with the authority to prescribe, adopt, and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

The proposed new section implements Tax Code, §171.0002.

§3.581. Margin: Taxable and Nontaxable Entities.

(a) Effective date. The provisions of this section apply to franchise tax reports originally due on or after January 1, 2008.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Banking corporation--Each state, national, domestic, or foreign bank, whether organized under the laws of this state, another state, or another country, or under federal law, including a limited banking association organized under Finance Code, Title 3, Subtitle A, and each bank organized under §25(a), Federal Reserve Act (12 U.S.C. §§611 - 631) (edge corporations), but does not include a bank holding company as that term is defined by Bank Holding Company Act of 1956, §2, (12 U.S.C. §1841).

(2) Business trust--An entity as defined by Internal Revenue Code, Treasury Regulation, §301.7701-4(b).

(3) Corporation--An entity formed pursuant to Business Corporation Act, Non-Profit Corporation Act, Professional Corporation Act, or Business Organizations Code, Title 2 or 7, or other equivalent statute of this state or of another jurisdiction.

(4) Escrow--A legal arrangement whereby an asset is delivered to a third party to be held in trust or otherwise pending a contingency or the fulfillment of a condition or conditions in a contract.

(5) Estate of a natural person--An entity as defined by Internal Revenue Code, §7701(a)(30)(D), excluding an estate taxable as a business entity pursuant to Internal Revenue Code, Treasury Regulation, §301.7701-4(b).

(6) General partnership--A partnership as described in Revised Partnership Act, Article 6132b-1.01 et. seq., or Business Organizations Code, Title 4, Chapter 152, or an equivalent statute in another jurisdiction.

(7) Grantor trust--A trust as defined by Internal Revenue Code, §671 and §7701(a)(30)(E), excluding a trust taxable as a business entity pursuant to Treasury Regulation, §301.7701-4(b).

(8) Holding company--An entity that confines its activities to owning stock in, and supervising management of, other companies.

(9) Joint stock company--A common-law unincorporated business enterprise of natural persons possessing common capital with ownership interests represented by shares of stock.

(10) Joint Venture--A partnership engaged in the joint prosecution of a particular transaction for mutual profit.

(11) Limited liability company--An entity formed pursuant to Limited Liability Company Act, Article 1528n, or Business Organizations Code, Title 3 or 7, or an equivalent statute in another jurisdiction.

(12) Limited liability partnership--A partnership registered pursuant to Revised Partnership Act, Article 6132b-3.08, or Business Organizations Code, Title 4, Chapters 152 and 153, Subchapter H, or an equivalent statute in another jurisdiction.

(13) Limited partnership--A partnership formed pursuant to Revised Partnership Act, Article 6132a-1 or Business Organizations Code, Title 4, Chapter 153, or an equivalent statute in another jurisdiction.

(14) Natural person--A human being or the estate of a human being. The term does not include a purely legal entity given recognition as the possessor of rights, privileges, and responsibilities, such as a corporation, limited liability company, partnership, or trust.

(15) Partnership--A relationship referred to in Business Organizations Code, §152.051, and Revised Partnership Act, Article 6132b-2.02.

(16) Passive entity--A general or limited partnership or trust other than a business trust that meets the qualifications in Tax Code, §171.0003. See also §3.582 of this title (relating to Margin: Passive Entities).

(17) Professional association--An entity organized under Professional Association Act, Article 1528e, or Business Organizations Code, Title 7, Chapter 302, or an equivalent statute in another jurisdiction.

(18) Qualified REIT subsidiary--An entity as defined by Internal Revenue Code, §856(i)(2).

(19) Real Estate Investment Trust or REIT--An entity as defined by Internal Revenue Code, §856.

(20) Real Estate Mortgage Investment Conduit or REMIC--An entity as defined by Internal Revenue Code, §860D.

(21) Savings and loan association--A savings and loan association or savings bank, whether organized under the laws of this state, another state, or another country, or under federal law.

(22) Self-insurance trust--A trust created and operated according to the provisions of Insurance Code, Chapter 2212, or a predecessor statute.

(23) Sole proprietorship--A natural person carrying on business, if the business is not formed in a manner that limits the liability of the owner. It does not include single member limited liability companies or other entities treated as sole proprietorships for federal tax purposes.

(c) Taxable entities include:

(1) partnerships, both general and limited, unless excluded in subsection (d)(2) of this section;

(2) limited liability partnerships;

(3) corporations;

(4) banking corporations;

(5) savings and loan associations;

(6) limited liability companies;

(7) business trusts;

(8) professional associations;

(9) business associations;

(10) joint ventures, except joint operating or co-ownership arrangements meeting the requirements of Treasury Regulation 1.761-2(a)(3) that elect out of federal partnership treatment as provided by Internal Revenue Code, §761(a);

(11) joint stock companies;

(12) holding companies;

(13) combined groups (also see §3.590 of this title (relating to Margin: Combined Reporting)); and

(14) other legal entities.

(d) Nontaxable entities. The following entities are specifically excluded from the definition of taxable entities for purposes of imposition of the franchise tax:

(1) sole proprietorships (does not include single member limited liability companies);

(2) general partnerships where direct ownership is composed entirely of natural persons, and the liability of those persons is not limited (e.g. by registration as a limited liability partnership) under a statute of this state or another state;

(3) passive entities, as determined on a year to year basis (also see §3.582 of this title);

(4) entities exempt under Chapter 171, Subchapter B;

(5) grantor trusts, all of the grantors and beneficiaries of which are natural persons or charitable entities as described in Internal Revenue Code, §501(c)(3);

(6) estates of a natural person;

(7) escrows;

(8) REITs or qualified REIT subsidiaries provided that:

(A) the REIT holds interests in limited partnerships or other entities that are taxable entities and directly hold real estate; and

(B) the REIT does not directly hold real estate, other than real estate it occupies for business purposes; or

(9) REMICs;

(10) nonprofit self-insurance trusts;

(11) trusts qualified under Internal Revenue Code, §401(a); or

(12) trusts or other entities that are exempt under Internal Revenue Code, §501(c)(9).

(e) Single member limited liability company. An entity treated as a sole proprietorship for federal tax purposes is not a sole proprietorship for the purposes of this rule if it is formed in a manner that limits the liability of its owners or members.

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 August 27, 2007.

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Martin Cherry
General Counsel
Comptroller of Public Accounts
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-0387

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34 TAC §3.582

The Comptroller of Public Accounts proposes new §3.582, concerning margin: passive entities. This section implements House Bill 3, 79th Legislature, Third Called Session 2006 and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This section establishes guidelines to determine the qualification of an entity as passive under Tax Code, Chapter 171. Subsection (a) provides that this section only applies to franchise tax reports originally due on or after January 1, 2008. Subsection (b) defines words and terms used in the section. Subsection (c) lists the types of entities that may qualify as passive entities and the types of income that qualify as passive income. Subsection (d) lists certain income that is not considered passive. Subsection (e) provides that a passive entity may not receive more than 10% of its federal gross income from conducting an active trade or business. Subsection (f) lists activities that do not constitute an active trade or business. Subsection (g) establishes the reporting requirements for a passive entity.

John Heleman, Chief Revenue Estimator, has determined that for the first five-year period the rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that for each year of the first five years the rule is in effect, the public benefit anticipated as a result of enforcing the rule will be in providing guidance to entities that potentially qualify as passive entities under Tax Code, Chapter 171. This rule is adopted under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

This new section is proposed under Tax Code, §111.002 and §111.022, which provides the comptroller with the authority to prescribe, adopt and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

This new section implements Tax Code, §171.0003.

§3.582. Margin: Passive Entities.

(a) Effective Date. The provisions of this section apply to franchise tax reports originally due on or after January 1, 2008.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise:

(1) Active trade or business--For the purposes of this section only:

(A) an entity conducts an active trade or business if the activities include active operations that form a part of the process of earning income or profit, and the entity performs active management and operational functions;

(B) activities performed by the entity include activities performed by persons outside the entity, including independent contractors, to the extent that the persons perform services on behalf of the entity and those services constitute all or part of the entity's trade or business; or

(C) an entity conducts an active trade or business if assets, including royalties, patents, trademarks, and other intangible assets, held by the entity are used in the active trade or business of one or more related entities.

(2) Business trust--An entity as defined by Internal Revenue Code, Treasury Regulation, §301.7701-4(b).

(3) Federal gross income--Gross income as defined in Internal Revenue Code, §61(a).

(4) General partnership--A partnership as described in Revised Partnership Act, Article 6132b-1.01 et. seq., or Business Organizations Code, Title 4, Chapter 152, or an equivalent statute in another jurisdiction.

(5) Limited partnership--A partnership formed pursuant to Revised Partnership Act, Article 6132a-1, or Business Organizations Code, Title 4, Chapter 153, or an equivalent statute in another jurisdiction.

(6) Net capital gains--Net capital gains as defined under the Internal Revenue Code.

(7) Net gains--Net gains as defined under the Internal Revenue Code.

(8) Non-controlling interest--For the purposes of this section only, a less than 50% interest that is held by an investor, either directly or indirectly, in an investee.

(9) Security--

(A) an instrument defined by Internal Revenue Code, §475(c)(2), where the holder of the instrument has a non-controlling interest in the issuer/investee;

(B) an instrument described by Internal Revenue Code, §475(e)(2)(B), (C), (D);

(C) an interest in a partnership where the investor has a non-controlling interest in the investee;

(D) an interest in a limited liability company where the investor has a non-controlling interest in the investee; or

(E) a beneficial interest in a trust where the investor has a non-controlling interest in the investee.

(c) Qualification as a passive entity:

(1) to qualify as a passive entity, the entity must be one of the following:

(A) general partnership;

(B) limited partnership; or

(C) trust, other than a business trust; and

(2) at least 90% of an entity's federal gross income must consist of the following sources of income:

(A) dividends, interest, foreign currency exchange gain, periodic and nonperiodic payments with respect to notional principal contracts, option premiums, cash settlements or termination payments with respect to a financial instrument, and income from a limited liability company;

(B) distributive shares of partnership income to the extent that those distributive shares of income are greater than zero;

(C) net capital gains from the sale of real property, net gains from the sale of commodities traded on a commodities exchange, and net gains from the sale of securities; and

(D) royalties from mineral properties, bonuses from mineral properties, delay rental income from mineral properties and income from other nonoperating mineral interests.

(d) The income described by subsection (c)(2) of this section, does not include:

(1) rent; or

(2) income received by a nonoperator from mineral properties under a joint operating agreement if the nonoperator is a member of an affiliated group and another member of that group is the operator under the same joint operating agreement.

(e) Conducting an active trade or business. To be considered a passive entity, an entity may not receive more than 10% of its federal gross income from conducting an active trade or business. Income described by subsection (c)(2) of this section, may not be treated as income from conducting an active trade or business.

(f) Activities that do not constitute an active trade or business:

(1) ownership of a royalty interest or a nonoperating working interest in mineral rights;

(2) payment of compensation to employees or independent contractors for financial or legal services reasonably necessary for the operation of the entity; and

(3) holding a seat on the board of directors of an entity does not, by itself, constitute conduct of an active trade or business.

(g) Reporting requirement for a passive entity. If an entity meets all of the qualifications of a passive entity for the reporting period, the entity will owe no tax; however, the entity must file information to verify that the passive entity qualifications are met each year.

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 August 31, 2007.

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Martin Cherry
General Counsel
Comptroller of Public Accounts
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For further information, please call: (512) 475-0387

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34 TAC §3.583

The Comptroller of Public Accounts proposes new §3.583, concerning margin: exemptions. This section implements House Bill 3, 79th Legislature, Third Called Session 2006 and House Bill 3928, 80th Legislature, 2007, adding Tax Code, §171.088, which extends to entities other than corporations certain specific exemptions from franchise tax available to corporations, provided the entity qualifies for the exemption in the same manner and under the same conditions as a corporation. Subsection (a) provides that this section only applies to franchise tax reports due on or after January 1, 2008. Subsection (b) explains how to apply for a franchise tax exemption and identifies the information that must accompany the application. Subsection (c) describes the possible actions that the comptroller will take after considering the application. Subsection (d) describes the qualifications necessary to qualify for exemption as: an entity subject to insurance premiums taxes, an entity promoting the public interest, a religious organization, a charitable organization, an educational organization and a homeowners' association. Subsection (e) addresses the effects of a revocation, withdrawal or loss of an exemption and the notification responsibilities of the affected entity. Subsection (f) provides that an entity that is exempt from federal income tax under one of certain specified paragraphs of Internal Revenue Code, §501(c) establishes its exempt status by providing a copy of a current exemption letter from the Internal Revenue Service to the comptroller. Subsection (g) describes the essential attributes of a solar energy device to qualify for exemption under Tax Code, §171.056. Subsection (h) provides that an entity engaged solely in the business of recycling sludge, as defined in the Health & Safety Code, is exempt from franchise tax. Subsection (i) identifies certain entities that may apply for a provisional or temporary exemption and describes the information that must accompany the application. Subsection (j) addresses the requirements necessary for an entity to qualify for the trade show exemption and provides for notification requirements in certain circumstances. Subsection (k) provides that an entity organized under 12 U.S.C., §2071, or an agricultural credit association regulated by the Farm Credit Administration is exempt from franchise tax.

John Heleman, Chief Revenue Estimator, has determined that for the first five-year period the rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that for each year of the first five years the rule is in effect, the public benefit anticipated as a result of enforcing the rule will be in providing guidance to entities that are potentially exempt from the tax imposed under Tax Code, Chapter 171. This rule is adopted under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

The new section is proposed under Tax Code, §111.002 and §111.022, which provides the comptroller with the authority to prescribe, adopt and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

The new section implements Tax Code, §171.0002 and §171.088.

§3.583. Margin: Exemptions.

(a) Effective date. This section applies to franchise tax reports originally due on or after January 1, 2008.

(b) Application for exemption. An entity must apply for an exemption from franchise tax. An entity that is not a corporation, but whose activities would qualify it for a specific exemption under Tax Code, Chapter 171, Subchapter B, if it were a corporation, may qualify for the exemption from the tax in the same manner and under the same conditions as a corporation. See Tax Code, §171.088. For provisional exemptions for certain entities, see subsection (i) of this section; for trade show exemptions, see subsection (j) of this section.

(1) An entity that believes it is exempt from payment of franchise tax must furnish to the comptroller sufficient evidence to establish its exempt status. The entity claiming the exemption bears the burden to establish its entitlement to exempt status and any doubts will result in a denial of the application for exemption.

(2) Except as otherwise provided in subsections (e), (i), and (j) of this section, each entity must submit to the comptroller:

(A) a request for exemption in writing, which may require using forms developed by the comptroller for requesting exemptions, indicating the particular provision of Tax Code, Chapter 171, under which exemption is claimed;

(B) a detailed statement of the entity's past and current activities, if any, and its future plan of activities, both in relation to the manner in which the entity proposes to implement the purposes clause in its certificate of formation or application for registration;

(C) if the entity is a non-Texas entity, a file-stamped copy of the entity's formation document or its governing documents, and a current Certificate of Existence or other similar document from the Secretary of State or other authorized officer of the entity's home jurisdiction; and

(D) any additional information the comptroller may require to make a determination whether the entity is eligible for a franchise tax exemption.

(c) Actions by comptroller. Upon receipt of an application for exemption, the comptroller's representative will review the application and send the applicant a notification either granting the exemption or denying the exemption, or requesting additional information.

(1) If the exemption is granted, the exemption will be effective from the first date the entity was eligible for exemption. If the entity paid any franchise taxes prior to the comptroller's notification granting the exemption for a privilege period after the effective date of the exemption, the entity may request a refund, subject to the applicable statute of limitations. If the effective date of the exemption occurs after the beginning of a privilege period, the entity must pay through the end of such privilege period. An entity that has been subject to the tax and becomes eligible for exemption is liable for Tax Code, §171.0011, additional tax.

(2) If the exemption is denied or revoked, the entity may contest the denial or revocation by filing all reports due as required by the comptroller; and

(A) paying all amounts of tax, penalty, and interest due and requesting a refund hearing pursuant to the provisions of Tax Code, Chapter 111;

(B) paying all amounts of tax, penalty, and interest due, accompanying the payment with a written protest, and filing suit for the recovery of amounts paid pursuant to the provisions of Tax Code, Chapter 112; or

(C) requesting a redetermination hearing pursuant to Tax Code, §111.009, if the comptroller issues a deficiency determination.

(d) Qualification for exemption.

(1) Entities subject to insurance premium taxes. All insurance, surety, guaranty, fidelity and title insurance companies, title insurance agents, and other insurance organizations that are subject to the annual gross premiums tax levied by Insurance Code, Chapters 221 - 224, are exempt from payment of the franchise tax, regardless of whether any gross premiums taxes are actually paid in any given year. A non-admitted insurance company or organization that is required to pay a gross premium receipts tax during a tax year is exempted from the franchise tax for the same tax year. The exemption in this paragraph covers the periods upon which the franchise tax is based, provided the gross premium receipts tax is required to be paid on premiums received or written, as applicable, during the same period. For example, an insurance organization's gross premium receipts tax is due and payable on March 1, 2009, for premiums received during calendar year 2008. The entity would be exempt from franchise tax for the 2009 annual report covering the January 1, 2009 - December 31, 2009, privilege period, for margin attributable to calendar year 2008. An entity is subject to the franchise tax, however, for a tax year in any portion of which it is in violation of an order issued by the Texas Department of Insurance under Insurance Code, §2254.003(b) that is final after appeal or that is no longer subject to appeal.

(2) Those entities organized for the exclusive purpose of promoting the public interest of any county, city, town, or other area within the state, must show that promotion of the public interest is the exclusive purpose of the entity and not merely an incidental result. An entity will not be considered to be promoting the public interest if it engages in activities to promote or protect the private, business, or professional interests of its members or patronage.

(3) A nonprofit entity seeking franchise tax exemption as a religious organization must be an organized group of people regularly meeting for the primary purpose of holding, conducting, and sponsoring religious worship services according to the rites of their sect. The entity must be able to provide evidence of an established congregation showing that there is an organized group of people regularly attending these services. An entity that supports and encourages religion as an incidental part of its overall purpose, or one whose general purpose is furthering religious work or instilling its membership with a religious understanding, will not qualify for exemption under this provision. No part of the net earnings of the organization may inure to the benefit of any private party or individual other than as reasonable compensation for services rendered to the organization. Some examples of entities that do not meet the requirements for exemption under this definition are conventions or associations of churches, evangelistic associations, churches with membership consisting of family members only, missionary organizations, and groups that meet for the purpose of holding prayer meetings, Bible study or revivals. Although these organizations do not qualify for exemption under this category of exemption as religious organizations, they may qualify for the exemption under Tax Code, §171.063, if they obtain an exemption from the Internal Revenue Service (IRS) under Internal Revenue Code, §501(c).

(4) A nonprofit entity seeking a franchise tax exemption as organized for purely public charity must devote all or substantially all of its activities to the alleviation of poverty, disease, pain, and suffering by providing food, clothing, drugs, treatment, shelter, or psychological counseling directly to indigent or similarly deserving members of society with its funds derived primarily from sources other than fees or charges for its services. If an entity engages in any substantial activity other than the activities that are described in this paragraph, it will

not be considered as having been organized for purely public charity, and therefore, will not qualify for exemption under this provision. No part of the net earnings of the organization may inure to the benefit of any private party or individual other than as reasonable compensation for services rendered to the organization. Some examples of organizations that do not meet the requirements for exemption under this definition are fraternal organizations, lodges, fraternities, sororities, service clubs, veterans groups, mutual benefit or social groups, professional groups, trade or business groups, trade associations, medical associations, chambers of commerce, and similar organizations. Even though not organized for profit and performing services that are often charitable in nature, these types of organizations do not meet the requirements for exemption under this provision. Although these organizations do not qualify for exemption under this category of exemption as charitable organizations, they may qualify for the exemption under Tax Code, §171.063, if they obtain an exemption from the IRS under Internal Revenue Code, §501(c).

(5) A nonprofit entity seeking a franchise tax exemption as an educational organization must show that its activities are devoted solely to systematic instruction, particularly in the commonly accepted arts, sciences, and vocations, and has a regularly scheduled curriculum, using the commonly accepted methods of teaching, a faculty of qualified instructors, and an enrolled student body or students in attendance at a place where the educational activities are regularly conducted. An entity that has activities consisting solely of presenting public discussion groups, forums, panels, lectures, or other similar programs, may qualify for exemption under this provision, if the presentations provide instruction in the commonly accepted arts, sciences, and vocations. The entity will not be considered for exemption under this provision if the systematic instruction or educational classes are incidental to some other facet of the organization's activities. No part of the net earnings of the organization may inure to the benefit of any private party or individual other than as reasonable compensation for services rendered to the organization. Some examples of organizations that do not meet the requirements for exemption under this definition are professional associations, business leagues, information resource groups, research organizations, support groups, home schools, and organizations that merely disseminate information by distributing printed publications. Although these organizations do not qualify for exemption under this category of exemption as educational organizations, they may qualify for the exemption under Tax Code, §171.063, if they obtain an exemption from the IRS under Internal Revenue Code, §501(c).

(6) A nonprofit entity requesting franchise tax exemption as a homeowners' association must prove that it meets all requirements to qualify for the exemption. The entity must show that it is organized and operated to obtain, manage, construct, and maintain the property in or of a residential condominium or residential real estate development. The entity also must prove that the condominium project, or, for a real estate development, the related property, is legally restricted for use as residences. Furthermore, the entity must establish that the collective resident owners of individual lots, residences or units control at least 51% of the votes of the entity and that voting control, however acquired, is not held by: a single individual or family; one or more developers, declarants, banks, investors, or other similar parties. For example, an association is formed for a residential condominium consisting of 12 units with each unit being entitled to one vote. Each of five individuals separately owns and occupies one unit, a total of five units. A sixth individual owns two units, living in one unit and leasing the other. A seventh individual owns and leases the remaining five units. None of the owners are related. In determining whether the collective resident owners control at least 51% of the votes of the organization, the sixth owner is a resident owner regarding the one unit in which the owner lives and an investor regarding the other. The collective resident owners, therefore, have a total of six votes. Consequently, since the collective resident owners only have 50% of the votes of the entity, the association does not meet the requirement that the resident owners must control at least 51% of the votes of the organization. Accordingly, the entity does not qualify for the franchise tax exemption as a homeowners' association.

(e) Revocation, withdrawal, or loss of exemptions.

(1) An entity that no longer qualifies for the franchise tax exemption is required to notify the comptroller in writing of its change in status. Except as provided in paragraph (2) of this subsection, if at any time the comptroller has reason to believe that an exempt entity no longer qualifies for exemption, the comptroller's representative will notify the entity that its exempt status is under review. The comptroller's representative may request additional information necessary to ascertain the continued validity of the entity's exempt status. If the comptroller determines that an entity is no longer entitled to its exemption, notification to that effect will be sent to the entity. The effective date of revocation is the date the entity no longer qualified for the exemption. The day immediately following the date of withdrawal, loss, or revocation shall be the beginning date for determining the entity's privilege period and for all other purposes related to franchise tax.

(2) For nonprofit entities granted an exemption under Tax Code, §171.063, the revocation, withdrawal, or loss of the federal income tax exemption automatically terminates the franchise tax exemption. A nonprofit entity that no longer qualifies for the federal income tax exemption which was the basis for obtaining the franchise tax exemption must notify the comptroller in writing within 30 days of its change in status and must provide a copy of the notice of such revocation, withdrawal, or loss. The effective date of withdrawal or loss is the date of withdrawal or loss of the federal tax exemption. The effective date of a revocation is the date the IRS serves written notice of the revocation to the non-profit entity or the date the IRS serves written notice of revocation to the comptroller, whichever is earlier. The day immediately following the date of withdrawal, loss, or revocation shall be the entity's beginning date for determining its privilege periods and for all other purposes of the franchise tax.

(3) An electric cooperative entity previously exempted from franchise tax under Tax Code, §171.079, that subsequently participates in a joint powers agency thereby loses its franchise tax exemption. The commencing date of participation in the joint powers agency shall be considered the entity's beginning date for purposes of determining the entity's privilege periods and for all other purposes of the franchise tax. The electric cooperative must notify the comptroller in writing that it is a participant in a joint powers agency within 30 days after the commencing date of its participation.

(f) Federal exemption. A nonprofit organization that has been exempted from the federal income tax under the provisions of Internal Revenue Code, §501(c)(2), (3), (4), (5), (6), (7), (8), (9), (10), (16), (19) or (25), establishes its exempt status by furnishing to the comptroller a copy of a current exemption letter from the IRS.

(g) Solar energy device. For purposes of Tax Code, §171.056, the term "solar energy device" includes, but is not limited to:

(1) devices used in the conversion of solar thermal energy into electrical or mechanical power;

(2) devices used in the photovoltaic (solar cell) generation of electricity;

(3) systems used in the heating of water and the heating and cooling of structures by use of solar collectors to gather the sun's energy; and

(4) heat pumps used as an integral part of a system designed to make the best combined use of solar energy and conventional heating.

(h) Exemption for recycling operation. An entity engaged solely in the business of recycling sludge as defined by Health and Safety Code, Chapter 361, Solid Waste Disposal Act, §361.003, is exempt from franchise tax.

(i) Provisional exemptions.

(1) If established with the comptroller, the following entities may be granted a temporary exemption from franchise tax:

(A) a nonprofit entity that has applied for exemption from federal income tax under Internal Revenue Code, §501(c)(3), (4), (5), (6), (7), (8), (9), (10), (16), or (19); and

(B) an entity that has applied for exemption from federal income tax under Internal Revenue Code, §501(c)(2) or (25), if the entity or entities for which it holds title to property is either exempt from or not subject to the franchise tax.

(2) To obtain a temporary franchise tax exemption with the comptroller, an entity that has applied for but has not yet received a letter of exemption from the IRS must timely file with the comptroller:

(A) a copy of the application for recognition of exemption that has been filed with the IRS; and

(B) a copy of:

(i) a written notice from the IRS stating that the application for recognition of exemption has been received; or

(ii) a receipt as proof that the application has been sent to the IRS by means of the United States Postal Service, other carrier, or hand delivery to the IRS.

(3) Paragraphs (2)(A) and (2)(B)(ii) of this subsection, apply only if the organization has filed its application for recognition of exemption during the 14th or 15th month after its beginning date. Beginning date means:

(A) for an entity organized under the laws of this state, the date on which the entity's certificate of formation or other similar document takes effect; and

(B) for a foreign entity, the date on which the entity begins doing business in this state.

(4) If the information required in paragraphs (2)(A) and (2)(B)(i) of this subsection is provided in a timely manner, a 90-day provisional franchise tax exemption will be granted.

(5) An entity qualifying under paragraphs (2)(A) and (2)(B)(ii) of this subsection, will be granted a 90-day provisional exemption with the condition that a copy of the notice required in paragraph (2)(B)(i) of this subsection be provided to the comptroller within 30 days from the date of the letter notifying the entity of the provisional exemption. If the IRS notification is not provided within the 30-day period, the provisional exemption will be canceled. An entity whose provisional exemption is canceled will be subject to all tax, penalty, and interest that has accrued since the entity's beginning date.

(6) The information necessary for obtaining a temporary franchise tax exemption will be considered to be provided to the comptroller in a timely manner if:

(A) the application for recognition of exemption is provided to the IRS within their timely filing guidelines; and

(B) the information required in paragraphs (2)(A) and (2)(B)(i) or (2)(B)(ii) of this subsection, is postmarked within 15 months after the day that is the last day of a calendar month and that is nearest to the entity's beginning date.

(7) Before the expiration of the 90-day provisional exemption, the entity must provide the comptroller a copy of the letter from the IRS showing that the decision on the federal exemption is still pending or stating that the federal exemption is either granted or denied.

(8) If the comptroller is notified as required in paragraph (7) of this subsection, that the decision on the federal exemption is still pending, an extension of the provisional exemption may be considered.

(9) If the information in paragraph (7) of this subsection, is not provided as required, the provisional exemption may be canceled. If the provisional exemption is canceled, the entity will be responsible for all franchise tax reports and payments that have become due since its beginning date, and penalty and interest will be based on the original due date of each report.

(10) An entity that provides the comptroller a copy of the letter from the IRS stating that the federal exemption has been granted will be considered for franchise tax exemption under subsection (e) of this section.

(11) If the federal exemption is denied by the IRS, the entity is responsible for all franchise tax reports and payments that have become due since its beginning date and interest will be based on the original due date of each report. Late filing and payment penalties will be waived for any reports and payments postmarked within 90 days after the date of the final denial of the federal exemption. The penalty waiver process will begin when the entity submits a written request for penalty waiver and a copy of the letter denying the federal exemption when filing reports and payment.

(j) Trade show exemption. See Tax Code, §171.084, for the requirements for exemption for certain foreign entities that participate in trade shows in Texas.

(1) Notification to comptroller. Entities need not apply for an exemption under Tax Code, §171.084.

(A) If a foreign entity has obtained a registration or has already notified the comptroller that it is doing business in Texas, the entity must notify the comptroller in writing by the due date of the first report for which the entity is exempt that the report and payment are not due because the entity is exempt under Tax Code, §171.084. After such notification, the entity must notify the comptroller in writing only when the organization no longer qualifies for exemption.

(B) If a foreign entity has not obtained a registration or otherwise qualified to do business in the state, if applicable, and if the entity has not notified the comptroller that it is doing business in Texas, the entity must notify the comptroller in writing only when the entity no longer qualifies for exemption under Tax Code, §171.084. There is no need to apply for exemption as long as the entity qualifies for the exemption.

(2) Solicitation periods. If the solicitation of orders is conducted during more than five periods during the business period upon which tax is based as set out in Tax Code, §171.1532, the entity does not qualify for exemption.

(A) An entity with its fiscal year ending December 31, 2008, that filed a 2008 annual report, will not have to file and pay a 2009 annual report if it did not solicit orders for more than five periods during 2008.

(B) Assume a foreign entity participated in its first trade show in Texas on April 1, 2008. It also participated in trade shows in 2009 on January 1, March 1, May 1, June 1, August 1, and October 1. The entity's fiscal year ends are December 31, 2008, and 2009. The entity would be exempt for its initial report and payment (covering the privilege periods from April 1, 2008 - December 31, 2009) because it only solicited for one period from April 1, 2008 - December 31, 2008 (i.e., the business upon which the initial report is based). The entity would be required to file a 2010 annual report and pay tax, however, because it solicited for six periods from January 1, 2009 - December 31, 2009 (i.e., the period upon which the 2010 annual report is based).

(3) One hundred twenty hours. A solicitation period may not exceed 120 consecutive hours. If the solicitation of orders is conducted during a single period of more than 120 consecutive hours, the entity does not qualify for exemption. For example, an entity that meets the other requirements of Tax Code, §171.084, will meet the 120 hours requirement if the solicitation occurs Monday - Friday, but will not meet the 120 hours requirement if the solicitation occurs Monday - Saturday. If none of the solicitation limits prescribed in this subsection are exceeded, an entity may qualify for the exemption even if it leases space at a wholesale center for the entire period upon which the tax is based.

(k) An entity organized under 12 U.S.C. §2071, or an agricultural credit association regulated by the Farm Credit Administration is exempt from franchise tax.

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 August 27, 2007.

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Martin Cherry
General Counsel
Comptroller of Public Accounts
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For further information, please call: (512) 475-0387

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34 TAC §3.584

The Comptroller of Public Accounts proposes new §3.584, concerning margin: reports and payments. This section implements House Bill 3, 79th Legislature, Third Called Special Session, 2006 and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This section establishes guidelines for the filing of reports and payments under Tax Code, Chapter 171. Subsection (a) provides that this section only applies to franchise tax reports originally due on or after January 1, 2008. Subsection (b) details the filing requirements for nontaxable entities. Subsection (c) details the types of franchise tax reports due, due dates and the accounting period to be used on the reports. Subsection (d) details the calculation of margin and the criteria for use of the 0.5% tax rate. This subsection also provides qualifications for the no tax due threshold, the discount and the E-Z Computation. Subsection (e) relates to the calculation of penalty and interest on delinquent taxes. Subsection (f) provides details on filing amended reports. Subsection (g) relates to the examination of an entity's records during a comptroller audit. Subsection (h) relates to the payment of an estimated liability. Subsection (i) provides requirements on filing a public information report or an ownership information report.

John Heleman, Chief Revenue Estimator, has determined that for the first five-year period the rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that for each year of the first five years the rule is in effect, the public benefit anticipated as a result of enforcing the rule will be in providing guidance to entities that are required to file reports and remit payments under Tax Code, Chapter 171. This rule is adopted under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

The new section is proposed under Tax Code, §111.002, which provides the comptroller with the authority to prescribe, adopt, and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

The new section implements Tax Code, §§171.002, 171.0021, 171.101, 171.1016, 171.151, 171.152, 171.1532, 171.154, 171.201, 171.202, 171.203, and 171.212.

§3.584. Margin: Reports and Payments.

(a) Effective date. The provisions of this section apply to franchise tax reports originally due on or after January 1, 2008.

(b) Nontaxable entities. See §3.581 of this title (relating to Margin: Taxable and Nontaxable Entities) for information concerning nontaxable entities. Notification to comptroller, except for passive entities, see §3.582 (relating to Margin: Passive Entities):

(1) If a taxable entity has notified the comptroller that it is doing business in Texas, the entity must notify the comptroller in writing by the due date of the first report for which the entity qualifies as a nontaxable entity that the report and payment are not due because the entity qualifies as a nontaxable entity. After such notification, the entity must notify the comptroller in writing only when the entity no longer qualifies as a nontaxable entity.

(2) If a nontaxable entity has not notified the comptroller that it is doing business in Texas, the nontaxable entity must notify the comptroller in writing only when the entity no longer qualifies as a nontaxable entity.

(c) Reports and due dates.

(1) Each taxable entity subject to the franchise tax levied by Tax Code, §171.001, must file an initial franchise tax report, and thereafter an annual franchise tax report, and at the same time must pay the franchise tax and any applicable penalties and interest due by the taxable entity. It is the responsibility of a receiver to file franchise tax reports and pay the franchise tax of a taxable entity in receivership. A debtor in possession or the appointed trustee or receiver of a taxable entity in reorganization or arrangement proceedings under the Bankruptcy Act is responsible for filing franchise tax reports and paying the franchise tax prior to confirming and consummating the plan of reorganization or arrangement.

(A) "Beginning date" means:

(i) for a taxable entity chartered or organized in this state, the date on which the taxable entity's charter or organization takes effect; and

(ii) for a foreign taxable entity, the date on which the taxable entity begins doing business in this state.

(B) Initial report. Both the initial report and payment of the tax due, if any, are due no later than 89 days after the first anniversary date of the beginning date. The initial franchise tax report and payment are for the privilege periods beginning on the beginning date and ending on December 31 following the first anniversary of the beginning date. For example, if a Texas taxable entity is chartered on June 1, 2008, the payment due with the initial report will be for the privilege periods from June 1, 2008 - December 31, 2009. In addition, when the first anniversary occurs during the period from October 4 - December 31, there must also be computed and paid with the initial report an additional year's tax for the privilege period beginning on January 1 following the first anniversary and ending on the following December 31. For example, if a Texas taxable entity is chartered on November 1, 2008, the payment due with the initial report will be for the privilege periods from November 1, 2008 - December 31, 2010. The taxable margin computed on the initial report is based on the business done during the period beginning on the beginning date and ending on the last accounting period ending date for federal income tax purposes that is at least 60 days before the original due date of the initial report, or, if there is no such ending date, then ending on the day that is the last day of the calendar month nearest to the end of the taxable entity's first year of business.

(C) Annual report. The annual franchise tax report must be filed and the tax paid no later than May 15 of each year. The annual tax is paid for the privilege period of the calendar year in which the report is due. The taxable margin computed on an annual report is based on the business done during the period beginning with the day after the last date upon which tax was computed under Tax Code, Chapter 171 on a previous report, and ending with the last accounting period ending date for federal income tax purposes ending in the calendar year before the calendar year in which the report is originally due, or, if there is no such ending date, then ending on December 31 of the calendar year before the calendar year in which the report is originally due. A taxable entity that uses a 52 - 53 week accounting year end and has an accounting year ending the first four days of January of the year in which the annual report is originally due may use the preceding December 31 as the date through which taxable margin is computed.

(D) Extensions. See §3.1 of this title (relating to Request for extension of Time in Which to File Report), for extensions of time to file an initial or final report. See §3.585 of this title (relating to Margin: Extensions), for extensions of time to file an annual report.

(E) Final report. See §3.592 of this title (relating to Margin: Additional Tax) for information concerning the additional tax imposed by Tax Code, §171.0011.

(F) Transition. See §3.595 of this title (relating to Margin: Transition) for transitional information concerning tax rates and privilege periods as a result of certain legislative changes.

(G) Passive entities. See §3.582 of this title (relating to Margin: Passive Entities), for information concerning the reporting requirements for a passive entity.

(H) Combined reporting. Taxable entities that are part of an affiliated group engaged in a unitary business must file a combined group report in lieu of individual reports, except that a public information report or ownership information report must be filed for each member of the combined group. See §3.590 of this title (relating to Margin: Combined Reporting), for rules on filing a combined report.

(2) The postmark date (or meter-mark if there is no postmark) on the envelope in which the report or payment is received determines the date of filing.

(3) An information report must be filed, even if no tax is due. A taxable entity must file a no tax due information report for the privilege periods covered by an initial report or regular annual report in which no tax is due, as authorized under Tax Code, §171.204.

(d) Calculation of margin.

(1) Calculation. If a taxable entity qualifies to deduct cost of goods sold the entity must make an annual election by the due date of its return. This election may not be amended. A taxable entity's margin equals the least of three calculations:

(A) Total revenue minus cost of goods sold;

(B) Total revenue minus compensation; or

(C) Total revenue times 70%.

(2) Rate. A tax rate of 1.0% of taxable margin applies to most taxable entities. A tax rate of 0.5% of taxable margin applies to taxable entities primarily engaged in retail or wholesale trade under division F or G of the 1987 Standard Industrial Classification Manual published by the Federal Office of Management and Budget. A taxable entity is primarily engaged in retail or wholesale trade only if:

(A) the total revenue from its activities in retail and wholesale trade is greater than the total revenue from its activities in trades other than the retail and wholesale trade;

(B) less than 50% of the total revenue from activities in retail or wholesale trade comes from the sale of products it produces or products produced by an entity that is part of an affiliated group to which the taxable entity also belongs, except for those businesses under Major Group 58 (eating and drinking establishments); and

(C) the taxable entity does not provide retail or wholesale utilities, including telecommunications services, electricity or gas.

(3) No tax due. A taxable entity will owe no tax if its tax due is less than $1,000 or its total revenue is less than or equal to $300,000, or the amount determined under Tax Code, §171.006, per 12 month period on which the report is based. A taxable entity that does not owe any tax under this subsection must file a no tax due information report as authorized by subsection (c)(3) of this section.

(4) Discount. A taxable entity is entitled to a discount of the tax imposed as follows:

(A) If total revenue is greater than $300,000 and less than $400,000, the discount is 80% of tax due.

(B) If total revenue is greater than or equal to $400,000 and less than $500,000, the discount is 60% of tax due.

(C) If total revenue is greater than or equal to $500,000 and less than $700,000, the discount is 40% of tax due.

(D) If total revenue is greater than or equal to $700,000 and less than $900,000, the discount is 20% of tax due.

(5) E-Z Computation. A taxable entity with total revenue of $10 million or less may elect to pay the franchise tax by using the E-Z Computation method. Under the E-Z Computation a taxable entity's tax liability is computed by multiplying the taxable entity's total revenue times their apportionment factor times 0.575% (.00575) and subtracting any applicable discount as provided by paragraph (4) of this subsection. No other credits or adjustments are allowed if a taxable entity elects to compute its tax liability under the E-Z Computation.

(e) Penalty and interest on delinquent taxes.

(1) Tax Code, §171.362, imposes a 5.0% penalty on the amount of franchise tax due by a taxable entity that fails to report or

pay the tax when due. If any part of the tax is not reported or paid within 30 days after the due date, an additional 5.0% penalty is imposed on the amount of tax unpaid. There is a minimum penalty of $1.00. Delinquent taxes accrue interest beginning 60 days after the due date. For example, if payment is made on the 61st day after the due date, one day's interest is due. The annual rate of interest on delinquent taxes is the prime rate plus one percent, as published in The Wall Street Journal on the first day of each calendar year that is not a Saturday, Sunday, or legal holiday.

(2) When a taxable entity is issued an audit assessment or other underpayment notice based on a deficiency, penalties under Tax Code, §171.362, and interest are applied as of the date that the underpaid tax was originally due, including any extensions, not from the date of the deficiency determination or date the deficiency determination is final.

(3) A deficiency determination is final 30 days after the date on which the service of the notice of the determination is completed. Service by mail is complete when the notice is deposited with the United States Postal Service.

(A) The amount of a determination is due and payable 10 days after it becomes final. If the amount of the determination is not paid within 10 days after the day it became final, a penalty under Tax Code, §111.0081, of 10% of the tax assessed will be added. For example, if a deficiency determination is made in the amount of $1,000 tax (plus the initial penalty and interest), but the total amount of the deficiency is not paid until the 41st day after the deficiency notice is served, $1,200 plus interest would be due (i.e., $1,000 tax, $100 initial penalty for not paying when originally due, $100 penalty for not paying deficiency determination within 10 days after it became final, plus interest accrued to the date of payment at the applicable statutory rate).

(B) A petition for redetermination must be filed within 30 days after the date on which the service of the notice of determination is completed, or the redetermination is barred.

(C) A decision on a petition for redetermination becomes final 20 days after service on the petitioner of the notice of the decision. The amount of a determination is due and payable 20 days after the decision is final. If the amount of the determination is not paid within 20 days after the day the decision becomes final, a penalty under Tax Code, §111.0081, of 10% of the tax assessed will be added. Using the previous example, on the 41st day after service of the decision, $1,200 plus interest would be due (i.e., $1,000 tax, $100 initial penalty, $100 additional penalty and the applicable accrued interest).

(4) A jeopardy determination is final 20 days after the date on which the service of the notice is completed unless a petition for redetermination is filed before the determination becomes final. Service by mail is complete when the notice is deposited with the United States Postal Service. The amount of the determination is due and payable immediately. If the amount determined is not paid within 20 days from the date of service, a penalty, under Tax Code, §111.022, of 10% of the amount of tax and interest assessed will be added.

(5) If the comptroller determines that a taxable entity exercised reasonable diligence to comply with the statutory filing or payment requirements, the comptroller may waive penalties or interest for the late filing of a report or for a late payment. The taxable entity requesting waiver must furnish a detailed description of the circumstances that caused the late filing or late payment and the diligence exercised by the taxable entity in attempting to comply with the statutory requirements. See §3.5 of this title (relating to Waiver of Penalty or Interest) for additional information.

(6) If a taxable entity fails to comply with Tax Code, §171.212, the taxable entity is liable for a penalty of 10% of the tax that should have been reported and had not previously been reported to the comptroller under Tax Code, §171.212. This penalty is in addition to any other penalty provided by law.

(f) Amended reports. In filing an amended report, the taxable entity must type or print on the report, immediately above the taxable entity name, the phrase "Amended Report." The report should be forwarded with a cover letter of explanation, with enclosures necessary to support the amendment. Applicable penalties and interest must be reported and paid along with any additional amount of tax shown to be due on the amended report.

(1) A taxable entity may file an amended report for the purpose of correcting a mathematical or other error in a report or for the purpose of supporting a claim for refund. An amended report may not be filed to change between a cost of goods sold deduction and a compensation deduction.

(2) A taxable entity that has been audited by the Internal Revenue Service must file an amended franchise tax report within 120 days after the Revenue Agent's Report (RAR) is final, if the RAR results in changes to taxable margin reported for franchise tax purposes. An RAR is final when all administrative appeals with the Internal Revenue Service have been exhausted or waived. An administrative appeal with the Internal Revenue Service does not include an action or proceeding in the United States Tax Court or any other federal court.

(3) A taxable entity whose taxable margin is changed as a result of an audit or other adjustment by a competent authority other than the Internal Revenue Service must file an amended franchise tax report within 120 days after the adjustment is final. An adjustment is final when all administrative or other appeals have been exhausted or waived. For the purposes of this section, a competent authority includes, but is not limited to, the United States Tax Court, United States District Courts, United States Courts of Appeals, and United States Supreme Court.

(4) A taxable entity must file an amended franchise tax report within 120 days after the taxable entity files an amended federal income tax return that changes the taxable entity's taxable margin. A taxable entity is considered to have filed an amended federal income tax return if the taxable entity is a member of an affiliated group during a period in which an amended consolidated federal income tax return is filed.

(5) A final determination resulting from an Internal Revenue Service administrative proceeding (including an audit), or a judicial proceeding arising from an administrative proceeding, that affects the amount of franchise tax liability must be reported to the comptroller before the expiration of 120 days after the day on which the determination becomes final. See Tax Code, §111.206.

(6) Because the 10% penalty provided for in Tax Code, §171.212 only applies to deficiencies, failure to file an amended return in which a refund would result will not cause a 10% penalty to be imposed.

(g) Comptroller audit. During the course of an audit or other examination of a taxable entity's franchise tax account, the comptroller may examine financial statements, working papers, registers, memoranda, contracts, corporate minutes, and any other business papers used in connection with its accounting system. In connection with the examination, the comptroller may also examine any of the taxable entity's officers or employees under oath.

(h) Payment of determination. The payment of a determination issued to a taxable entity for an estimated tax liability shall not

satisfy the reporting requirements set forth in Tax Code, Chapter 171, Subchapter E, concerning reports and records.

(i) Information report. Each taxable entity on which the franchise tax is imposed must file an information report.

(1) For a taxable entity other than a corporation or limited liability company, an ownership information report as described in Tax Code, §171.201 and §171.202 is due at the same time each initial and annual report is due.

(2) For a corporation or limited liability company a public information report as described in Tax Code, §171.203, is due at the same time each initial and annual report is due. An authorized person must sign the public information report on behalf of the taxable entity under a certification that:

(A) all information contained in the report is true and correct to the best of the authorized person's knowledge; and

(B) a copy of the report has been mailed to each person named in the report who is an officer, director, or manager and who is not employed by the taxable entity or a related (at least 10% ownership) taxable entity on the date the report is filed.

(C) A report that is filed electronically complies with the signature and certification requirements of this provision.

(3) Failure to file or sign a public information report or ownership information report shall result in the forfeiture of corporate or business privileges as provided by Tax Code, §171.251 and §171.2515. If the corporate or business privileges are forfeited, each officer or director of the taxable entity may be liable for each debt of the taxable entity that is created or incurred in Texas after the date on which the report is due and before the corporate or business privileges are revived, as provided by Tax Code, §171.255.

(4) The provisions of paragraph (3) of this subsection, concerning forfeiture of corporate privileges do not apply to a banking taxable entity or a savings and loan association, as defined in Tax Code, §171.001.

(5) For purposes of this subsection:

(A) authorized person means, in the case of a corporation, an officer, director or other authorized person of the corporation;

(B) authorized person means, in the case of a limited liability company, a member, manager or other authorized person of the limited liability company;

(C) authorized person means, in the case of a limited partnership, a partner or other authorized person of the partnership;

(D) director includes a manager of a limited liability company, a general partner in a limited partnership and a general partner in a partnership registered as a limited liability partnership.

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 August 27, 2007.

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Martin Cherry
General Counsel
Comptroller of Public Accounts
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For further information, please call: (512) 475-0387

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34 TAC §3.585

The Comptroller of Public Accounts proposes new §3.585, concerning margin: annual report extensions. This section implements House Bill 3, 79th Legislature, Third Called Session 2006 and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This section establishes guidelines for requesting extensions under Tax Code, Chapter 171. Subsection (a) provides the effective date. Subsection (c) provides guidance for an extension to November 15. Subsection (d) states an extension will not be granted by paying 100% of the tax paid in the previous year if no report was filed for the previous year, or due in the previous year. Subsection (e) provides guidance for calculating penalty and interest. Subsections (f) - (h) provide guidance for extensions for taxpayers required to file by electronic funds transfer. Subsection (i) states no additional extensions will be granted, other than those provided for in this section.

John Heleman, Chief Revenue Estimator, has determined that for the first five-year period the rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that for each year of the first five years the rule is in effect, the public benefit anticipated as a result of enforcing the rule will be in providing guidance to taxpayers regarding obtaining extensions for filing annual reports required under Tax Code, Chapter 171. This rule is adopted under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

The new section is proposed under Tax Code, §111.002, which provides the comptroller with the authority to prescribe, adopt, and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

The new section implements Tax Code, §171.202.

§3.585. Margin: Annual Report Extensions.

(a) Effective date. The provisions of this section apply to franchise tax reports originally due on or after January 1, 2008.

(b) Taxable and nontaxable entities. See §3.581 of this title (relating to Margin: Taxable and Nontaxable Entities) for a list of taxable and nontaxable entities.

(c) Extension to November 15. Except for a taxable entity which has been notified by the comptroller that it is required to make its franchise tax payments by electronic funds transfer (see subsections (d), (f), and (g) of this section), a taxable entity will be granted an extension to file an annual report on or before the next November 15, if the taxable entity:

(1) requests the extension on or before May 15;

(2) requests the extension on a form provided by the comptroller; and

(3) remits with the extension request:

(A) 90% or more of the amount of tax reported as due on the report filed on or before November 15; or

(B) 100% of the tax reported as due for the previous calendar year on the report due in the previous calendar year and filed on or before May 14 of the year for which the extension is requested.

(d) No previous report. An extension shall not be granted under subsections (c)(3)(B) or (f)(3)(B) of this section, if no report was due in the previous calendar year or the report due in the previous calendar year is not filed on or before May 14 of the year for which the extension is requested.

(e) Penalty and interest. Penalty and interest, except for a taxable entity which has been notified by the comptroller that it is required to make its franchise tax a payments by electronic funds transfer (see subsection (h) of this section), will be calculated as though the following were due dates.

(1) If a taxable entity is granted an extension and pays, on or before May 15, at least 100% of the tax reported as due for the previous calendar year on the report due in the previous calendar year and filed on or before May 14 of the year for which the extension is requested, then November 15 will be the due date for any additional tax due.

(2) If a taxable entity is granted an extension and pays on or before May 15, 90% or more of the tax which will be reported as due on or before November 15, then November 15 will be the due date for any additional tax due.

(3) If a taxable entity, on or before May 15, requests an extension but does not qualify for an extension under paragraphs (1) or (2) of this subsection, then May 15 is the due date for 90% of the tax finally determined to be due and November 15 is the due date for 10% of the tax finally determined to be due.

(f) Required electronic funds transfer extension to August 15. A taxable entity which has been notified by the comptroller that it is required to make its franchise tax payments by electronic funds transfer (see §3.9 of this title (relating to Electronic Filing of Returns and Reports; Electronic Transfer of Certain Payments by Certain Taxpayers)) will be granted an extension to file an annual report on or before the next August 15, if the taxable entity:

(1) requests the extension on or before May 15;

(2) requests the extension on a form provided by the comptroller; and

(3) remits with the extension request:

(A) 90% or more of the amount of tax reported as due on the report filed on or before November 15; or

(B) 100% of the tax reported as due for the previous calendar year on the report due in the previous calendar year and filed on or before May 14 of the year for which the extension is requested.

(g) Required electronic funds transfer extension to November 15. A taxable entity granted an extension under subsection (f) of this section, will be granted an extension to file an annual report on or before the next November 15, if the taxable entity:

(1) requests the extension on or before August 15;

(2) requests the extension on a form provided by the comptroller; and

(3) remits with the request the difference between the amount paid previously for the current reporting period and 100% of the amount of tax reported as due on the report filed on or before November 15.

(h) Required electronic funds transfer penalty and interest. Penalty and interest will be calculated as though the following were due dates.

(1) If a taxable entity is granted an extension until August 15 and pays, on or before May 15, at least 100% of the tax reported as due for the previous calendar year on the report due in the previous calendar year and filed on or before May 14 of the year for which the extension is requested, then August 15 will be the due date for any additional tax due. However, if the taxable entity requests, on or before August 15, an extension until November 15, and remits, on or before August 15, 99% of the amount reported as due on or before November 15, then November 15 will be the due date for any additional tax due.

(2) If a taxable entity is granted an extension until August 15 and pays, on or before May 15, 90% or more of the tax which will be reported as due on or before August 15, then August 15 will be the due date for any additional tax due. However, if the taxable entity requests, on or before August 15, an extension until November 15, and remits, on or before August 15, 99% of the amount reported as due on or before November 15, then November 15 will be the due date for any additional tax due.

(3) If a taxable entity, on or before May 15, requests an extension until August 15, but does not qualify for an extension under paragraphs (1) or (2) of this subsection, then May 15 is the due date for 90% of the tax finally determined to be due. August 15 is the due date for the remaining 10% of the tax finally determined to be due. However, if the taxable entity requests, on or before August 15, an extension until November 15, and remits on or before August 15 at least 99% of the amount reported as due on or before November 15, then May 15 is the due date for 90% of the amount reported as due on or before November 15, August 15 is the due date for 90% of the amount reported as due on or before November 15, and November 15 is the due date for any additional tax due.

(i) No additional extensions. No additional extensions will be granted for annual franchise tax reports pursuant to Tax Code, §111.057.

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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34 TAC §3.586

The Comptroller of Public Accounts proposes new §3.586, concerning margin: nexus. This section implements House Bill 3, 79th Legislature, Third Called Session, 2006 and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This section establishes guidelines for determining nexus under Tax Code, Chapter 171. Subsection (a) provides the effective date. Subsection (b) states that Texas will find nexus to the limits of the United States Constitution. Subsection (c) provides a non-exclusive list of common activities which will subject a taxable entity to Texas franchise tax. Subsection (e) states Public Law 86-272 does not apply to the franchise tax.

John Heleman, Chief Revenue Estimator, has determined that for the first five-year period the rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that for each year of the first five years the rule is in effect, the public benefit anticipated as a result of enforcing the rule will be in providing guidance to entities regarding activities in Texas that would subject an entity to franchise tax. This rule is adopted under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

The new section is proposed under Tax Code, §111.002, which provides the comptroller with the authority to prescribe, adopt, and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

The new section implements Tax Code, §171.001 and §171.106.

§3.586. Margin: Nexus.

(a) Effective date. The provisions of this section apply to franchise tax reports originally due on or after January 1, 2008.

(b) A taxable entity is subject to franchise tax in this state when it has sufficient contact with this state to be taxed without violating the United States Constitution.

(c) Some specific activities which subject a taxable entity to Texas franchise tax include, but are not limited to, the following:

(1) advertising: entering Texas to purchase, place, or display advertising when the advertising is for the benefit of another and in the ordinary course of business (e.g., the foreign taxable entity makes signs and brings them into Texas, sets them up, and maintains them);

(2) consignments: having consigned goods in Texas;

(3) contracting: performance of a contract in Texas regardless of whether the taxable entity brings its own employees into the state, hires local labor, or subcontracts with another;

(4) delivering: delivering into Texas items it has sold;

(5) employees or representatives: having employees or representatives in Texas doing the business of the taxable entity;

(6) federal enclaves: doing business in any area within Texas, even if the area is leased by, owned by, ceded to, or under the control of the federal government;

(7) franchisors: entering into one or more contracts with persons, corporations, or other business entities located in Texas, by which:

(A) the franchisee is granted the right to engage in the business of offering, selling, or distributing goods or services under a marketing plan or system prescribed in substantial part by the franchisor; and

(B) the operation of a franchisee's business pursuant to such plan is substantially associated with the franchisor's trademark, service mark, trade name, logotype, advertising, or other commercial symbol designating the franchisor or its affiliate.

(8) holding companies: maintaining a place of business in Texas or managing, directing, and/or performing services in Texas for subsidiaries or investee entities;

(9) inventory: having an inventory in Texas or having spot inventory for the convenient delivery to customers, even if the bulk of orders are filled from out of state;

(10) leasing: leasing tangible personal property which is used in Texas;

(11) loan production activities: soliciting sales contracts or loans, gathering financial data, making credit checks, collecting accounts, repossessing property or performing other financial activities in Texas through employees, independent contractors, or agents, regardless of whether they reside in Texas;

(12) partners:

(A) acting as a general partner in a general partnership which is doing business in Texas;

(B) acting as a general partner in a limited partnership which is doing business in Texas (a foreign taxable entity which is a limited partner in a limited partnership is not doing business in Texas, if that is the limited partner's only connection with Texas);

(13) place of business: maintaining a place of business in Texas;

(14) processing: assembling, processing, manufacturing, or storing goods in Texas;

(15) real estate: holding, acquiring, leasing, or disposing of any property located in Texas;

(16) services, including, but not limited to the following:

(A) providing any service in Texas, regardless of whether the employees, independent contractors, agents, or other representatives performing the services reside in Texas;

(B) maintaining or repairing property located in Texas whether under warranty or by separate contract;

(C) installing, erecting, or modifying property in Texas;

(D) conducting training classes, seminars or lectures in Texas;

(E) providing any kind of technical assistance in Texas, including, but not limited to, engineering services; or

(F) investigating, handling or otherwise assisting in resolving customer complaints in Texas.

(17) shipment: sending materials to Texas to be stored awaiting orders for their shipment;

(18) shows and performances: the staging of or participating in shows, theatrical performances, sporting events, or other events within Texas;

(19) solicitation: having employees, independent contractors, agents, or other representatives in Texas, regardless of whether they reside in Texas, to promote or induce sales of the foreign taxable entity's goods or services;

(20) telephone listing: having a telephone number that is answered in Texas; or

(21) transportation:

(A) carrying passengers or freight (any personal property including oil and gas transmitted by pipeline) from one point in Texas to another point within the state, if pickup and delivery, regardless of origination or ultimate destination, occurs within Texas; or

(B) having facilities and/or employees, independent contractors, agents, or other representatives in Texas, regardless of whether they reside in Texas:

(i) for storage, delivery, or shipment of goods;

(ii) for servicing, maintaining, or repair of vehicles, trailers, containers, and other equipment;

(iii) for coordinating and directing the transportation of passengers or freight; or

(iv) for doing any other business of the taxable entity.

(d) See §3.583 of this title (relating to Margin: Exemptions) for information concerning exemption for certain trade show participants under Tax Code, §171.084.

(e) Public Law 86-272 (15 United States Code §§381 - 384) does not apply to the franchise tax.

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 August 27, 2007.

TRD-200703924
Martin Cherry
General Counsel
Comptroller of Public Accounts
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-0387

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34 TAC §3.587

The Comptroller of Public Accounts (Comptroller) proposes new §3.587, concerning Margin: Total Revenue. This proposed new section implements House Bill 3, 79th Legislature, Third Called Session 2006 and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This new section establishes guidelines for determining total revenue under Tax Code, Chapter 171. Subsection (a) provides that this new section only applies to franchise tax reports due on or after January 1, 2008. Subsection (b) defines words and terms used in this section. Subsection (c) provides general rules used in the calculation of total revenue. Subsection (d) details the line items from federal income tax forms that each type of entity will use in determining total revenue and also details certain subtractions from total revenue. Subsection (e) details items that are excluded from total revenue.

John Heleman, Chief Revenue Estimator, has determined that, for the first five-year period the proposed new rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that, for each year of the first five years proposed new the rule is in effect, the public benefit anticipated as a result of enforcing the rule will be in providing guidance to taxpayers for computing total revenue under Tax Code, Chapter 171. This new rule is proposed under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed new rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

This new section is proposed under Tax Code, §111.002 and §111.022, which provides the Comptroller with the authority to prescribe, adopt and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

This proposed new section implements Tax Code, §171.1011.

§3.587. Margin: Total Revenue.

(a) Effective date. The provisions of this section apply to franchise tax reports originally due on or after January 1, 2008.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Actual costs of uncompensated care--Uncompensated care divided by total charges multiplied by the result of total operating expenses less compensation.

(A) Total charges means all amounts for health care services, including uncompensated care.

(B) Compensation includes amounts determined under Tax Code, §171.1013, regardless of whether the taxable entity elects to subtract compensation. See §3.589 (relating to Margin: Compensation).

(2) Federal obligations--

(A) stocks and other direct obligations of, and obligations unconditionally guaranteed by, the United States government and United States government agencies; and

(B) direct obligations of a United States government-sponsored agency.

(3) Health care institution--Any of the following types of institutions: an ambulatory surgical center; an assisted living facility licensed under Health and Safety Code, Chapter 247; an emergency medical services provider; a home and community support services agency; a hospice; a hospital; a hospital system; an intermediate care facility for the mentally retarded or a home and community-based services waiver program for persons with mental retardation adopted in accordance with the federal Social Security Act, §1915(c) (42 U.S.C. §1396n); a birthing center; a nursing home; an end stage renal disease facility licensed under Health and Safety Code, §251.011; or a pharmacy.

(4) Health care provider--Any taxable entity that participates in the Medicaid program, Medicare program, Children's Health Insurance Program (CHIP), state workers' compensation program, or TRICARE military health system as a provider of health care services.

(5) Lending institution--An entity that makes loans and;

(A) is regulated by the Federal Reserve Board, the Office of the Comptroller of the Currency, the Federal Deposit Insurance Corporation, the Commodity Futures Trading Commission, the Office of Thrift Supervision, the Texas Department of Banking, the Office of Consumer Credit Commissioner, the Credit Union Department, or any comparable regulatory body;

(B) is licensed by, registered with, or otherwise regulated by the Department of Savings and Mortgage Lending;

(C) is a "broker" or "dealer" as defined by the Securities Exchange Act of 1934 at 15 U.S.C. §78c; or

(D) provides financing to unrelated parties solely for agricultural production.

(6) Management company--A corporation, limited liability company, or other limited liability entity that conducts all or part of the active trade or business of another entity ("the managed entity") in exchange for:

(A) a management fee; and

(B) reimbursement of specified costs incurred in the conduct of the active trade or business of the managed entity, including wages and cash compensation as determined under Tax Code, §171.1013(a) and (b).

(7) Net distributive income--The net amount of income, gain, deduction, or loss relating to a pass-through entity or disregarded entity reportable to the owners for the tax year of the entity.

(8) Obligation--Any bond, debenture, security, mortgage-backed security, pass-through certificate, or other evidence of indebtedness of the issuing entity. The term does not include a deposit, a repurchase agreement, a loan, a lease, a participation in a loan or pool of loans, a loan collateralized by an obligation of a United States government agency, or a loan guaranteed by a United States government agency.

(9) Pro bono services--The direct provision of legal services to the poor, without an expectation of compensation.

(10) Product--Tangible personal property.

(11) Sales commission--

(A) any form of compensation paid to a person for engaging in an act for which a license is required by Occupations Code, Chapter 1101; or

(B) compensation paid to a sales representative by a principal in an amount that is based on the amount or level of certain orders for or sales of the principal's product and that the principal is required to report on Internal Revenue Service Form 1099-MISC (or would have been reported if the amount had met the Internal Revenue Service minimum reporting requirement).

(C) for purposes of defining sales commission, a principal is a person who:

(i) manufactures, produces, imports, distributes, or acts as an independent agent for the distribution of a product for sale;

(ii) uses a sales representative to solicit orders for the product; and

(iii) compensates the sales representative wholly or partly by sales commission.

(12) Security--The meaning assigned by Internal Revenue Code, §475(c)(2), and includes instruments described by Internal Revenue Code, §475(e)(2)(B), (C), and (D).

(13) Staff leasing services company--A business entity that offers staff leasing services, as that term is defined by Labor Code, §91.001, or a temporary employment service, as that term is defined by Labor Code, §93.001.

(14) Tiered partnership arrangement--An ownership structure in which any of the interests in one taxable entity treated as a partnership or an S corporation for federal income tax purposes (a "lower tier entity") are owned by one or more other taxable entities (an "upper tier entity").

(15) Uncompensated care--Standard charges for the health care services provided by a health care provider, where the provider has not received any payment for health care provided to the patient.

(16) United States government--Any department or ministry of the federal government, including a federal reserve bank. The term does not include a state or local government, a commercial enterprise owned wholly or partly by the United States government, or a local governmental entity or commercial enterprise whose obligations are guaranteed by the United States government.

(17) United States government agency--An instrumentality of the United States government whose obligations are fully and explicitly guaranteed as to the timely payment of principal and interest by the full faith and credit of the United States government. The term includes the Government National Mortgage Association, the Department of Veterans Affairs, the Federal Housing Administration, the Farmers Home Administration, the Export-Import Bank, the Overseas Private Investment Corporation, the Commodity Credit Corporation, the Small Business Administration, and any successor agency.

(18) United States government-sponsored agency--An agency originally established or chartered by the United States government to serve public purposes specified by the United States Congress but whose obligations are not explicitly guaranteed by the full faith and credit of the United States government. The term includes the Federal Home Loan Mortgage Corporation, the Federal National Mortgage Association, the Farm Credit System, the Federal Home Loan Bank System, the Student Loan Marketing Association, and any successor agency.

(c) General rules for reporting total revenue.

(1) Variant of form. Any reference to an Internal Revenue Service form includes a variant of the form. For example, a reference to Form 1120 includes Forms 1120-A, 1120-S, and other variants of Form 1120. A reference to an Internal Revenue Service form also includes any subsequent form with a different number or designation that substantially provides the same information as the original form.

(2) Amount reportable. Any reference to an amount reportable as income on a line number on an Internal Revenue Service form is the amount entered to the extent the amount entered complies with federal income tax law and includes the corresponding amount entered on a variant of the form, or a subsequent form, with a different line number to the extent the amount entered complies with federal income tax law.

(3) Federal consolidated group. A taxable entity that is part of a federal consolidated group or is a disregarded entity shall compute its total revenue as if it had filed a separate return for federal income tax purposes. Further information on total revenue for combined entities can be found in §3.590 of this title (relating to Margin: Combined Reporting).

(4) Passive entity. A taxable entity will include its share of net distributive income from a passive entity, but only to the extent the net income of the passive entity was not generated by any other taxable entity.

(5) Exclusions from total revenue. For any revenue that is excluded from total revenue, the related costs may not be included in the determination of cost of goods sold (see §3.588 of this title (relating to Margin: Costs of Goods Sold)) or the determination of compensation (see §3.589 of this title (relating to Margin: Compensation)).

(6) Contract services. Except as provided by subsection (e)(2) of this section, a payment received under an ordinary contract

for the provision of services in the ordinary course of business may not be excluded from the calculation of total revenue.

(7) Revenue from affiliated group members. If the taxable entity belongs to an affiliated group, the taxable entity may not exclude from the calculation of total revenue any payments described by subsection (e)(1) - (6) of this section that are made to entities that are members of the affiliated group.

(8) Lower tier entities. A lower tier entity in a tiered partnership arrangement may not exclude from total revenue any revenue reported to an upper tier entity, regardless of whether the upper tier entity includes the revenue from the lower tier entity in the upper tier entity's calculation of taxable margin.

(9) Allocated revenue. Revenue that Texas cannot tax because the activities generating that item of revenue do not have sufficient unitary connection with the entity's other activities conducted in Texas under the United States Constitution is not included in total revenue.

(10) No federal return. A taxable entity that is not exempt under Tax Code, Chapter 171, and the State of Texas is not prohibited from taxing because of treaty, federal law or the United States Constitution, must calculate its franchise tax based on a proforma federal return, if the taxable entity does not file a federal return.

(d) Reporting total revenue. The line items in this subsection refer to line items on the 2006 Internal Revenue Service forms. In computing total revenue for a subsequent report year, total revenue should be based on the equivalent line numbers from the corresponding federal report and computed based on the Internal Revenue Code of 1986 in effect for the federal tax year beginning on January 1, 2007.

(1) Corporations. For the purpose of computing its taxable margin, the total revenue of a taxable entity treated as a corporation for federal income tax purposes is computed by:

(A) adding:

(i) the amount reportable as income on line 1c, Internal Revenue Service Form 1120;

(ii) the amounts reportable as income on lines 4 through 10, Internal Revenue Service Form 1120; and

(iii) any total revenue reported by a lower tier entity as includable in the taxable entity's total revenue under Tax Code, §171.1015(b); and

(B) subtracting, to the extent included in the calculation under subparagraph (A) of this paragraph:

(i) bad debt expensed for federal income tax purposes that corresponds to items of gross receipts included for the current reporting period or a past reporting period;

(ii) foreign royalties and foreign dividends from an affiliated taxable entity that does not transact a substantial portion of its business or regularly maintain a substantial portion of its assets in the United States, including amounts determined under Internal Revenue Code, §78 or §§951 - 964;

(iii) net distributive income from a taxable entity treated as a partnership or as an S corporation for federal income tax purposes, except as provided by subsection (c)(4) of this section;

(iv) allowable deductions from Internal Revenue Service Form 1120, Schedule C, to the extent the relating dividend income is included in total revenue;

(v) items of income attributable to an entity that is a disregarded entity for federal income tax purposes; and

(vi) other amounts authorized by subsection (e) of this section.

(2) S corporations. For the purpose of computing its taxable margin, the total revenue of a taxable entity treated as an S corporation for federal income tax purposes is computed by:

(A) adding:

(i) the amount reportable as income on line 1c, Internal Revenue Service Form 1120S;

(ii) the amounts reportable as income on lines 4 and 5, Internal Revenue Service Form 1120S; and

(iii) the amounts reportable as income on lines 3a and 4 through 10, Internal Revenue Service Form 1120S, Schedule K;

(iv) the amounts reportable as income on line 17, Internal Revenue Service Form 8825;

(v) any total revenue reported by a lower tier entity as includable in the taxable entity's total revenue under Tax Code, §171.1015(b); and

(B) subtracting, to the extent included in the calculation under subparagraph (A) of this paragraph:

(i) bad debt expensed for federal income tax purposes that corresponds to items of gross receipts included for the current reporting period or a past reporting period;

(ii) foreign royalties and foreign dividends from an affiliated taxable entity that does not transact a substantial portion of its business or regularly maintain a substantial portion of its assets in the United States, including amounts determined under Internal Revenue Code, §78 or §§951 - 964;

(iii) net distributive income from a taxable entity treated as a partnership or as an S corporation for federal income tax purposes, except as provided by subsection (c)(4) of this section;

(iv) items of income attributable to an entity that is a disregarded entity for federal income tax purposes; and

(v) other amounts authorized by subsection (e) of this section.

(3) Partnerships. For the purpose of computing its taxable margin, the total revenue of a taxable entity treated as a partnership for federal income tax purposes is computed by:

(A) adding:

(i) the amount reportable as income on line 1c, Internal Revenue Service Form 1065;

(ii) the amounts reportable as income on lines 4, 6, and 7, Internal Revenue Service Form 1065;

(iii) the amounts reportable as income on lines 3a and 5 through 11, Internal Revenue Service Form 1065, Schedule K;

(iv) the amounts reportable as income on line 17, Internal Revenue Service Form 8825;

(v) the amounts reportable as income on line 11, plus line 2 or line 45, Internal Revenue Service Form 1040, Schedule F; and

(vi) any total revenue reported by a lower tier entity as includable in the taxable entity's total revenue under Tax Code, §171.1015(b); and

(B) subtracting, to the extent included in the calculation under subparagraph (A) of this paragraph:

(i) bad debt expensed for federal income tax purposes that corresponds to items of gross receipts included for the current reporting period or a past reporting period;

(ii) foreign royalties and foreign dividends from an affiliated taxable entity that does not transact a substantial portion of its business or regularly maintain a substantial portion of its assets in the United States, including amounts determined under Internal Revenue Code, §78 or §§951 - 964;

(iii) net distributive income from a taxable entity treated as a partnership or as an S corporation for federal income tax purposes, except as provided by subsection (c)(4) of this section;

(iv) items of income attributable to an entity that is a disregarded entity for federal income tax purposes; and

(v) other amounts authorized by subsection (e) of this section.

(4) Trusts. For the purpose of computing its taxable margin, the total revenue of a taxable entity treated as a trust for federal income tax purposes is computed by:

(A) adding:

(i) the amount reportable as income on lines 1, 2a, 3, 4, 7, and 8 of Internal Revenue Service Form 1041;

(ii) the amount reportable as income on lines 3, 4, 32, and 37 of Internal Revenue Service Form 1040, Schedule E; and

(iii) the amounts reportable as income on line 11, plus line 2 or line 45, Internal Revenue Service Form 1040, Schedule F; and

(iv) any total revenue reported by a lower tier entity as includable in the taxable entity's total revenue under Tax Code, §171.1015(b); and

(B) subtracting, to the extent included in the calculation under subparagraph (A) of this paragraph:

(i) bad debt expensed for federal income tax purposes that corresponds to items of gross receipts included for the current reporting period or a past reporting period;

(ii) foreign royalties and foreign dividends from an affiliated taxable entity that does not transact a substantial portion of its business or regularly maintain a substantial portion of its assets in the United States, including amounts determined under Internal Revenue Code, §78 or §§951 - 964;

(iii) net distributive income from a taxable entity treated as a partnership or as an S corporation for federal income tax purposes, except as provided by subsection (c)(4) of this section;

(iv) items of income attributable to an entity that is a disregarded entity for federal income tax purposes; and

(v) other amounts authorized by subsection (e) of this section.

(5) Single member limited liability company (LLC) filing as a sole proprietorship. For the purpose of computing its taxable margin, the total revenue of a taxable entity registered as a single member limited liability company and filing as a sole proprietorship for federal income tax purposes is computed by:

(A) adding:

(i) the amount reportable as income on line 3 of Internal Revenue Service, Form 1040, Schedule C;

(ii) the amount reportable as income on line 17, Internal Revenue Service Form 4797, to the extent that it relates to the LLC;

(iii) ordinary income or loss from partnerships, S corporations, estates and trusts, Internal Revenue Service Form 1040, Schedule E, to the extent that it relates to the LLC;

(iv) the amount reportable as income on line 16 of Internal Revenue Service Form 1040, Schedule D, to the extent that it relates to the LLC;

(v) the amounts reportable as income on lines 3 and 4, Internal Revenue Service Form 1040, Schedule E, to the extent that it relates to the LLC;

(vi) the amounts reportable as income on line 11, plus line 2 or line 45, Internal Revenue Service Form 1040, Schedule F, to the extent that it relates to the LLC;

(vii) the amount reportable as income on line 6 of Internal Revenue Service Form 1040, Schedule C, that has not already been included in this subparagraph; and

(viii) any total revenue reported by a lower tier entity as includable in the taxable entity's total revenue under Tax Code, §171.1015(b); and

(B) subtracting, to the extent included in the calculation under subparagraph (A) of this paragraph:

(i) bad debt expensed for federal income tax purposes that corresponds to items of gross receipts included for the current reporting period or a past reporting period;

(ii) foreign royalties and foreign dividends from an affiliated taxable entity that does not transact a substantial portion of its business or regularly maintain a substantial portion of its assets in the United States, including amounts determined under Internal Revenue Code, §78 or §§951 - 964;

(iii) net distributive income from a taxable entity treated as a partnership or as an S corporation for federal income tax purposes, except as provided by subsection (c)(4) of this section;

(iv) items of income attributable to an entity that is a disregarded entity for federal income tax purposes; and

(v) other amounts authorized by subsection (e) of this section.

(6) Other taxable entities. For a taxable entity other than a taxable entity treated for federal income tax purposes as a corporation, S corporation, partnership, trust, or single member limited liability company filing as a sole proprietorship, the total revenue will be an amount determined in a manner substantially equivalent to the amount calculated for the entities listed in this subsection.

(e) Exclusions from total revenue. Except as otherwise provided in this section and only to the extent included in the calculation of total revenue under subsection (d)(1) - (6) of this section, the following items shall be excluded from total revenue:

(1) Flow-through funds mandated by law. Flow-through funds that are mandated by law or fiduciary duty to be distributed to other entities, including taxes collected from a third party by the taxable entity and remitted by the taxable entity to a taxing authority;

(2) Flow-through funds mandated by contract. Flow-through funds that are mandated by contract to be distributed to other entities, limited to:

(A) sales commissions, as that term is defined by subsection (b)(11) of this section, to non-employees, including split-fee real estate commissions;

(B) the tax basis as determined under the Internal Revenue Code of securities underwritten; and

(C) subcontracting payments handled by the taxable entity to provide services, labor, or materials in connection with the actual or proposed design, construction, remodeling, or repair of improvements on real property or the location of the boundaries of real property;

(3) Principal repayments. A taxable entity shall exclude the principal repayment of loans;

(4) Tax basis of securities and loans. A taxable entity shall exclude the tax basis, as determined under the Internal Revenue Code, of securities and loans sold;

(5) Legal services. A taxable entity that provides legal services shall exclude:

(A) the following flow-through funds that are mandated by law, contract, or fiduciary duty to be distributed to the claimant by the claimant's attorney or to other entities on behalf of a claimant by the claimant's attorney:

(i) damages due the claimant;

(ii) funds subject to a lien or other contractual obligation arising out of the representation, other than fees owed to the attorney;

(iii) funds subject to a subrogation interest or other third-party contractual claim; and

(iv) fees paid an attorney in the matter who is not a member, partner, shareholder, or employee of the taxable entity;

(B) reimbursement of the taxable entity's expenses incurred in prosecuting a claimant's matter that are specific to the matter and that are not general operating expenses; and

(C) regardless of whether it was included in the calculation of total revenue under subsection (d) of this section, $500 per pro bono services case handled by the attorney, but only if the attorney maintains records of the pro bono services for auditing purposes in accordance with the manner in which those services are reported to the State Bar of Texas;

(6) Pharmacy cooperative. A taxable entity that is a pharmacy cooperative shall exclude flow-through funds from rebates from pharmacy wholesalers that are distributed to the pharmacy cooperative's shareholders;

(7) Staff leasing services company. A taxable entity that is a staff leasing services company shall exclude payments received from a client company for wages, payroll taxes on those wages, employee benefits, and workers' compensation benefits for the assigned employees of the client company;

(8) Dividends and interest from federal obligations. A taxable entity shall exclude dividends and interest received from federal obligations;

(9) Management company. A taxable entity that is a management company shall exclude reimbursements of specified costs incurred in its conduct of the active trade or business of a managed entity, including wages and cash compensation as determined under Tax Code, §171.1013(a) and (b);

(10) Health care provider. A taxable entity that is a health care provider shall exclude:

(A) the total amount of payments received:

(i) under the Medicaid program, Medicare program, Indigent Health Care and Treatment Act (Health and Safety Code, Chapter 61), and Children's Health Insurance Program (CHIP);

(ii) for professional services provided in relation to a workers' compensation claim under Labor Code, Title 5; and

(iii) for professional services provided to a beneficiary rendered under the TRICARE military health system; and

(B) the actual costs, regardless of whether it was included in the calculation of total revenue under subsection (d)(1) - (6) of this section, of uncompensated care provided, but only if the provider maintains records of the uncompensated care for auditing purposes and, if the provider later receives payment for all or part of that care, the provider adjusts the amount excluded for the tax year in which the payment is received.

(11) Health care institution. A health care provider that is a health care institution shall exclude 50 percent of the exclusion described in paragraph (10) of this subsection.

(12) Federal government and armed forces. A taxable entity shall exclude all revenue received that is directly derived from the operation of a facility that is:

(A) located on property owned or leased by the federal government; and

(B) managed or operated primarily to house members of the armed forces of the United States.

(13) Oil and gas. During the dates, certified by the comptroller, in which the monthly average closing price of West Texas Intermediate crude oil is below $40 per barrel and the average closing price of gas is below $5 per MMBtu, as recorded on the New York Mercantile Exchange (NYMEX), a taxable entity shall exclude total revenue received from oil or gas produced from:

(A) an oil well designated by the Railroad Commission of Texas or similar authority of another state whose production averages less than 10 barrels a day over a 90-day period; and

(B) a gas well designated by the Railroad Commission of Texas or similar authority of another state whose production averages less than 250 mcf a day over a 90-day period.

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 August 28, 2007.

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Martin Cherry
General Counsel
Comptroller of Public Accounts
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-0387

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34 TAC §3.588

The Comptroller of Public Accounts (Comptroller) proposes new §3.588, concerning Margin: Cost of Goods Sold. This proposed new section implements House Bill 3, 79th Legislature, Third Called Session, 2006 and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This new section establishes guidelines for computing cost of goods sold under Tax Code, Chapter 171. Subsection (a) provides that this new section only applies to franchise tax reports originally due on or after January 1, 2008. Subsection (b) defines words and terms used in the new section. Subsection (c) provides general rules for computing cost of goods sold. Subsection (d) details the direct costs includable in cost of goods sold. Subsection (e) details additional costs includable in cost of goods sold. Subsection (f) relates to indirect and administrative overhead costs includable in costs of goods sold. Subsection (g) details those costs not includable in cost of goods sold.

John Heleman, Chief Revenue Estimator, has determined that, for the first five-year period the proposed new rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that, for each year of the first five years the proposed new rule is in effect, the public benefit anticipated as a result of enforcing the new rule will be in providing guidance to businesses subject to the franchise tax regarding the computation of cost of goods sold under Tax Code, Chapter 171. This new rule is proposed under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed new rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

This new section is proposed under Tax Code, §111.002 and §111.022, which provides the Comptroller with the authority to prescribe, adopt and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

This proposed new section implements Tax Code, §171.1012.

§3.588. Margin: Cost of Goods Sold.

(a) Effective Date. The provisions of this section apply to franchise tax reports originally due on or after January 1, 2008.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Arm's length--The standard of conduct under which entities that are not related parties and that have substantially equal bargaining power, each acting in its own interest, would negotiate or carry out a particular transaction.

(2) Computer program--A series of instructions that are coded for acceptance or use by a computer system and that are designed to permit the computer system to process data and provide results and information. The series of instructions may be contained in or on magnetic tapes, printed instructions, or other tangible or electronic media.

(3) Goods--Real or tangible personal property sold in the ordinary course of business of a taxable entity. "Goods" includes:

(A) the husbandry of animals;

(B) the growing and harvesting of crops;

(C) the severance of timber from realty.

(4) Heavy construction equipment--Self-propelled, self-powered, or pull-type equipment that weighs at least 3,000 pounds and is intended to be used for construction. The term does not include a motor vehicle required to be titled and registered.

(5) Lending institution--An entity that makes loans and:

(A) is regulated by the Federal Reserve Board, the Office of the Comptroller of the Currency, the Federal Deposit Insurance Corporation, the Commodity Futures Trading Commission, the Office of Thrift Supervision, the Texas Department of Banking, the Office of Consumer Credit Commissioner, the Credit Union Department, or any comparable regulatory body;

(B) is licensed by, registered with, or otherwise regulated by the Department of Savings and Mortgage Lending;

(C) is a "broker" or "dealer" as defined by the Securities Exchange Act of 1934 at 15 U.S.C. §78c; or

(D) provides financing to unrelated parties solely for agricultural production.

(6) Principal business activity--The activity in which a taxable entity derives the largest percentage of its "total revenue".

(7) Production--Construction, manufacture, installation occurring during the manufacturing process, development, mining, extraction, improvement, creation, raising, or growth.

(8) Related party--A person, corporation, or other entity, including an entity that is treated as a pass-through or disregarded entity for purposes of federal taxation, whether the person, corporation, or entity is subject to the tax under this chapter or not, in which one person, corporation, or entity, or set of related persons, corporations, or entities, directly or indirectly owns or controls a controlling interest in another entity.

(9) Tangible personal property--

(A) includes:

(i) personal property that can be seen, weighed, measured, felt, or touched or that is perceptible to the senses in any other manner;

(ii) films, sound recordings, videotapes, live and prerecorded television and radio programs, books, and other similar property embodying words, ideas, concepts, images, or sound, without regard to the means or methods of distribution or the medium in which the property is embodied, for which, as costs are incurred in producing the property, it is intended or is reasonably likely that any medium in which the property is embodied will be mass-distributed by the creator or any one or more third parties in a form that is not substantially altered; and

(iii) a computer program, as defined in paragraph (2) of this subsection.

(B) does not include:

(i) intangible property or

(ii) services.

(10) Undocumented worker--A person who is not lawfully entitled to be present and employed in the United States.

(c) General rules for determining cost of goods sold.

(1) Affiliated entities. Notwithstanding any other provision of this section, a payment made by one member of an affiliated

group to another member of that affiliated group not included in the combined group may be subtracted as a cost of goods sold only if it is a transaction made at arm's length.

(2) Capitalization or expensing of certain costs. A taxable entity that is allowed a subtraction by this section for a cost of goods sold and that is subject to Internal Revenue Code, §§263A, 460, or 471, may:

(A) Capitalize that cost in the same manner and to the same extent that the taxable entity capitalized that cost on its federal income tax return, except for those costs excluded under subsection (g) of this section, or in accordance with subsections (d), (e), and (f) of this section.

(i) If the taxable entity elects to capitalize costs, it must capitalize each cost allowed under this section that it capitalized on its federal income tax return.

(ii) If the taxable entity later elects to begin expensing a cost that may be allowed under this section as a cost of goods sold, the entity may not deduct any cost in ending inventory from a previous report.

(B) Expense those costs, except for those costs excluded under subsection (g) of this section, or in accordance with subsections (d), (e), and (f) of this section.

(i) If the taxable entity elects to expense a cost of goods sold that may be allowed under this section, a cost incurred before the first day of the period on which the report is based may not be subtracted as a cost of goods sold.

(ii) If the taxable entity later elects to begin capitalizing a cost that may be allowed under this section as a cost of goods sold, a cost expensed on a previous report may not be capitalized.

(3) Exclusions from total revenue. Costs related to revenue that has been excluded from total revenue (see §3.587 of this title (relating to Margin: Total Revenue)) may not be included in the determination of cost of goods sold. Costs must be allocated between included and excluded revenue on a reasonable basis.

(4) Film and broadcasting. A taxable entity whose principal business activity is film or television production or broadcasting or the sale of broadcast rights or the distribution of tangible personal property described by subsection (b)(9)(A)(ii) of this section, or any combination of these activities, and who elects to use cost of goods sold to determine margin, may include as cost of goods sold:

(A) the costs described in this section in relation to the property;

(B) depreciation, amortization, and other expenses directly related to the acquisition, production, or use of the property, including

(C) expenses for the right to broadcast or use the property.

(5) Lending institutions. Notwithstanding any other provision of this section, if the taxable entity is a lending institution that offers loans to the public and elects to subtract cost of goods sold, the entity may subtract as a cost of goods sold an amount equal to interest expense.

(A) This paragraph does not apply to entities primarily engaged in an activity described by category 5932 of the 1987 Standard Industrial Classification Manual published by the federal Office of Management and Budget.

(B) For purposes of this subsection, an entity engaged in lending to unrelated parties solely for agricultural production offers loans to the public.

(6) Owner of goods. A taxable entity may make a subtraction under this section in relation to the cost of goods sold only if that entity owns the goods. The determination of whether a taxable entity is an owner is based on all of the facts and circumstances, including the various benefits and burdens of ownership vested with the taxable entity.

(A) A taxable entity furnishing labor or materials to a project for the construction, improvement, remodeling, repair, or industrial maintenance (as the term "maintenance" is defined in §3.357 of this title (relating to Nonresidential Real Property Repair, Remodeling, and Restoration; Real Property Maintenance)), of real property is considered to be an owner of the labor or materials and may include the costs, as allowed by this section, in the computation of goods sold.

(B) Solely for the purposes of this section, a taxable entity shall be treated as the owner of goods being manufactured or produced by the entity under a contract with the federal government, including any subcontracts that support a contract with the federal government, notwithstanding that the Federal Acquisition Regulation may require that title or risk of loss with respect to those goods be transferred to the federal government before the manufacture or production of those goods is complete.

(7) Rentals and leases. Notwithstanding any other provision of this section, the following taxable entities may subtract as cost of goods sold the costs otherwise allowed by this section in relation to tangible personal property that the entity rents or leases in the ordinary course of business of the entity:

(A) a motor vehicle rental or leasing company that remits a tax on gross receipts imposed under Tax Code, §152.026;

(B) a heavy construction equipment rental or leasing company; and

(C) a railcar rolling stock rental or leasing company.

(8) Reporting methods. A taxable entity shall determine its cost of goods sold, except as otherwise provided by this section, in accordance with the methods used on the federal income tax return on which the report under this chapter is based. This subsection does not affect the type or category of cost of goods sold that may be subtracted under this section.

(9) Restaurants. Entities engaged in activities described in Major Group 58 of the Standard Industrial Classification Manual may deduct for cost of goods sold only those expenses allowed under subsections (d), (e) and (f) of this section, that relate to the production of food. Any costs related to both the production of food and to other activities must be allocated to production on a reasonable basis.

(d) Cost of goods sold. The cost of goods sold includes all direct costs of acquiring or producing the goods, including:

(1) labor costs including W-2 wages, IRS Form 1099 wages, temporary labor, payroll taxes and benefits;

(2) cost of materials that are an integral part of specific property produced;

(3) cost of materials that are consumed in course of performing production activities;

(4) handling costs, including costs attributable to processing, assembling, repackaging, and inbound transportation;

(5) storage costs, including the costs of carrying, storing, or warehousing property;

(6) depreciation, depletion, and amortization, reported on the federal income tax return on which the report under this chapter is based, to the extent associated with and necessary for the production of goods, including recovery described by Internal Revenue Code, §197, and property described in Internal Revenue Code, §179;

(7) the cost of renting or leasing equipment, facilities, or real property used for the production of the goods, including pollution control equipment and intangible drilling and dry hole costs;

(8) the cost of repairing and maintaining equipment, facilities, or real property directly used for the production of the goods, including pollution control devices;

(9) costs attributable to research, experimental, engineering, and design activities directly related to the production of the goods, including all research or experimental expenditures described by Internal Revenue Code, §174;

(10) geological and geophysical costs incurred to identify and locate property that has the potential to produce minerals;

(11) taxes paid in relation to acquiring or producing any material, or taxes paid in relation to services that are a direct cost of production;

(12) the cost of producing or acquiring electricity sold; and

(13) a contribution to a partnership in which the taxable entity owns an interest that is used to fund activities, the costs of which would otherwise be treated as cost of goods sold of the partnership, but only to the extent that those costs are related to goods distributed to the contributing taxable entity as goods-in-kind in the ordinary course of production activities rather than being sold by the partnership.

(e) Additional costs. In addition to the amounts includable under subsection (d) of this section, the cost of goods sold includes the following costs in relation to the taxable entity's goods:

(1) deterioration of the goods;

(2) obsolescence of the goods;

(3) spoilage and abandonment, including the costs of rework, reclamation, and scrap;

(4) if the property is held for future production, preproduction direct costs allocable to the property, including storage and handling costs, as provided by subsection (d)(4) and (5) of this section;

(5) postproduction direct costs allocable to the property, including storage and handling costs, as provided by subsection (d)(4) and (5) of this section;

(6) the cost of insurance on a plant or a facility, machinery, equipment, or materials directly used in the production of the goods;

(7) the cost of insurance on the produced goods;

(8) the cost of utilities, including electricity, gas, and water, directly used in the production of the goods;

(9) the costs of quality control, including replacement of defective components pursuant to standard warranty policies, inspection directly allocable to the production of the goods, and repairs and maintenance of goods; and

(10) licensing or franchise costs, including fees incurred in securing the contractual right to use a trademark, corporate plan, manufacturing procedure, special recipe, or other similar right directly associated with the goods produced.

(f) Indirect or administrative overhead costs. A taxable entity may subtract as a cost of goods sold indirect or administrative overhead costs that it can demonstrate are allocable to the acquisition or production of goods. This amount may not exceed 4.0% of total indirect or administrative overhead cost.

(1) Indirect or administrative overhead costs include, but are not limited to, all mixed service costs, such as security services, legal services, data processing services, accounting services, personnel operations, and general financial planning and financial management costs.

(2) Any costs already subtracted under subsections (d) or (e) of this section, may not be subtracted under this subsection.

(3) Any costs excluded under subsection (g) of this section, may not be subtracted under this subsection.

(g) Costs not included. The cost of goods sold does not include the following costs in relation to the taxable entity's goods:

(1) the cost of renting or leasing equipment, facilities, or real property that is not used for the production of the goods;

(2) selling costs, including employee expenses related to sales;

(3) distribution costs, including outbound transportation costs;

(4) advertising costs;

(5) idle facility expenses;

(6) rehandling costs;

(7) bidding costs, which are the costs incurred in the solicitation of contracts ultimately awarded to the taxable entity;

(8) unsuccessful bidding costs, which are the costs incurred in the solicitation of contracts not awarded to the taxable entity;

(9) interest, including interest on debt incurred or continued during the production period to finance the production of the goods;

(10) income taxes, including local, state, federal, and foreign income taxes, and franchise taxes that are assessed on the taxable entity based on income;

(11) strike expenses, including costs associated with hiring employees to replace striking personnel, but not including the wages of the replacement personnel, costs of security, and legal fees associated with settling strikes;

(12) officers' compensation;

(13) costs of operation of a facility that is:

(A) located on property owned or leased by the federal government; and

(B) managed or operated primarily to house members of the armed forces of the United States;

(14) any compensation paid to an undocumented worker used for the production of goods; and

(15) costs funded by a partnership contribution, to the extent that the contributing taxable entity made the cost of goods sold deduction under subsection (d)(13) of 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 August 28, 2007.

TRD-200703926
Martin Cherry
General Counsel
Comptroller of Public Accounts
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-0387

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34 TAC §3.589

The Comptroller of Public Accounts (Comptroller) proposes new §3.589, concerning Margin: Compensation. This proposed new section implements House Bill 3, 79th Legislature, Third Called Session, 2006 and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This new section establishes guidelines for computing compensation under Tax Code, Chapter 171. Subsection (a) provides that this new section only applies to franchise tax reports due on or after January 1, 2008. Subsection (b) defines words and terms used in the new section. Subsection (c) provides for general rules used in the calculation of compensation. Subsection (d) provides for exclusions from total compensation. Subsection (e) provides for general rules used in the calculation of benefits. Subsection (f) provides for general rules for staff leasing companies. Subsection (g) provides for general rules for management companies. Subsection (h) provides for rules applicable for small employers.

John Heleman, Chief Revenue Estimator, has determined that, for the first five-year period the proposed new rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that, for each year of the first five years the proposed new rule is in effect, the public benefit anticipated as a result of enforcing the new rule will be in providing guidance to businesses subject to the franchise tax regarding the computation of compensation under Tax Code, Chapter 171. This new rule is proposed under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed new rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

This new rule is proposed under Tax Code, §111.002, which provides the Comptroller with the authority to prescribe, adopt, and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

The proposed new section implements Tax Code, §171.1011 and §171.1013.

§3.589. Margin: Compensation.

(a) Effective date. The provisions of this section apply to franchise tax reports originally due on or after January 1, 2008.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Assigned employee--Has the meaning assigned by Labor Code, §91.001.

(2) Client company--

(A) a person that contracts with a license holder under Labor Code, Chapter 91, and is assigned employees by the license holder under that contract; or

(B) a client of a temporary employment service, as that term is defined by Labor Code, §93.001(2), to whom individuals are assigned for a purpose described by that subdivision.

(3) Management company--A corporation, limited liability company or other limited liability entity that conducts all or part of the active trade or business of another entity (the managed entity) in exchange for:

(A) a management fee; and

(B) reimbursement of specified costs incurred in the conduct of the active trade or business of the managed entity.

(4) Natural person--A human being or the estate of a human being. The term does not include a purely legal entity given recognition as the possessor of rights, privileges, or responsibilities, such as a corporation, limited liability company, partnership, or trust.

(5) Net distributive income--The net amount of income, gain, deduction, or loss relating to a pass-through entity or disregarded entity reportable to the owners for the tax year of the entity.

(6) Small employer--An entity defined in Insurance Code, §1501.002.

(7) Staff leasing services company--A business entity that offers staff leasing services as that term is defined by Labor Code, §91.001, or temporary employment service as that term is defined by Labor Code, §93.001.

(8) Undocumented worker--A person who is not lawfully entitled to be present and employed in the United States.

(9) Wages and cash compensation--

(A) the amount entered in the Medicare wages and tips box of Internal Revenue Service Form W-2 or any subsequent form with a different number or designation that substantially provides the same information;

(B) the amount of net distributive income from one of the following entities to partners or owners during the accounting period but only if the person receiving the amount is a natural person:

(i) taxable entities treated as partnerships for federal income tax purposes;

(ii) limited liability companies and corporations treated as S corporations for federal income tax purposes; and

(iii) limited liability companies treated as sole proprietorships for federal income tax purposes;

(C) stock awards and stock options deducted for federal income tax purposes, to the extent not included in subparagraph (A) of this paragraph.

(c) Compensation. Subject to Tax Code, §171.1014, a taxable entity that elects to subtract compensation for the purpose of computing its taxable margin under Tax Code, §171.101, may subtract an amount equal to:

(1) subject to subsection (d) of this section, all wages and cash compensation paid by a taxable entity to its officers, directors, owners, partners and employees. The taxable entity cannot subtract more than $300,000, or the amount determined under Tax Code, §171.006, for any one person in wages and cash compensation it

determines under Tax Code, §171.101. See §3.590 of this title (relating to Margin: Combined Reporting); and

(2) subject to subsection (e) of this section, the cost of all benefits the taxable entity provides to its officers, directors, owners, partners, and employees;

(d) Compensation- excluded items. Compensation does not include:

(1) payments to independent contractors on Forms 1099;

(2) exclusions from revenue. See §3.587 of this title (relating to Margin: Total Revenue). Compensation related to any revenue excluded from total revenue may not be included in the determination of compensation. Compensation must be allocated between included and excluded revenue on a reasonable basis;

(3) an employer's share of payroll taxes;

(4) wages or cash compensation paid to an employee whose primary employment is directly associated with the operation of a facility that is located on property owned or leased by the federal government, and managed or operated primarily to house members of the armed forces of the United States. See §3.587 of this title; and

(5) wages or cash compensation paid to undocumented workers.

(e) Benefits. A taxable entity is allowed to subtract the cost of all benefits to the extent deductible for federal income tax purposes that it provides to its officers, directors, owners, partners, and employees.

(1) The term "benefits" includes employer contributions made to:

(A) employees' health savings accounts;

(B) health care (for example, this would include contributions to the cost of health insurance);

(C) retirement; and

(D) workers' compensation.

(2) The term "benefits" does not include the following:

(A) amounts included in the definition of wages and cash compensation;

(B) discounts on the price of the taxable entity's merchandise or services sold to the taxpayer's employees, officers, or directors, partners, or owners that are not available to other customers;

(C) payroll taxes. (For example, "payroll taxes" would include payments to state and federal unemployment compensation funds and payments under the Federal Insurance Contributions Act, Chapter 21 of Subtitle C of the Internal Revenue Code, §§3101 - 3128, the Railroad Retirement Tax Act, Chapter 22 of Subtitle C of the Internal Revenue Code, §§3201 - 3233); and

(D) working condition amounts provided so employees can perform their jobs. (Examples of working condition benefits include an employee's use of a company car for business, job-related education provided to an employee, and travel reimbursement.)

(3) The cost of benefits does not include the amount paid by an employee.

(f) Staff leasing companies. See §3.587 of this title.

(1) A staff leasing company cannot subtract the following payments for assigned employees:

(A) wages and cash compensation;

(B) payroll taxes; and

(C) employee benefits including workers' compensation.

(2) A client company can subtract the following amounts for assigned employees:

(A) wages and cash compensation; and

(B) benefits.

(3) A client company cannot subtract the following:

(A) an administrative fee; and

(B) other costs.

(4) A staff leasing company shall determine compensation only for the taxable entity's own employees who are not assigned employees.

(g) Management company. See §3.587 of this title.

(1) A taxable entity that is a management company may not include as wages and cash compensation any amounts reimbursed by a managed entity.

(2) A taxable entity that is a managed entity may subtract wages and cash compensation that are reimbursed to the management company.

(3) A management company shall determine compensation for only those wages and compensation payments that are not reimbursed by a managed entity.

(h) Small employers. This subsection applies to a taxable entity that is a small employer and that has not provided health care benefits to any of its employees in the calendar year preceding the beginning date of its reporting period. Subject to Tax Code, §171.1014, a taxable entity to which this subsection applies that elects to subtract compensation for the purpose of computing its taxable margin under Tax Code, §171.101, may subtract the following health care benefits:

(1) amounts as provided under subsection (c) of this section;

(2) for the first 12-month period on which margin is based and in which the taxable entity provides health care benefits to all of its employees, an additional amount equal to 50% of the cost of health care benefits provided to its employees for that period; and

(3) for the second 12-month period on which margin is based and in which the taxable entity provides health care benefits to all of its employees, an additional amount equal to 25% of the cost of health care benefits provided to its employees for that period.

(4) The term "provide" does not include amounts paid by the employee, officer, director, etc.

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 August 28, 2007.

TRD-200703927
Martin Cherry
General Counsel
Comptroller of Public Accounts
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-0387

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34 TAC §3.590

The Comptroller of Public Accounts (Comptroller) proposes new §3.590, concerning Margin: Combined Reporting. This proposed new section implements House Bill 3, 79th Legislature, Third Called Special Session, 2006 and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This new section establishes guidelines for combined reporting under Tax Code, Chapter 171. Subsection (a) provides that this new section only applies to franchise tax reports due on or after January 1, 2008. Subsection (b) defines words and terms used in the new section. Subsection (c) provides for mandatory combined reporting. Subsection (d) provides general rules for determining combined taxable margin and apportionment. Subsection (e) provides general rules describing the reporting entity's responsibilities. Subsection (f) provides general rules for determining the accounting period of the combined group. Subsection (g) addresses the liability for tax, interest, and penalty of the combined group and its members. Subsection (h) provides general rules for the calculation of credits. Subsection (i) provides general rules for calculating the tax rate.

John Heleman, Chief Revenue Estimator, has determined that, for the first five-year period the proposed new rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that, for each year of the first five years the proposed new rule is in effect, the public benefit anticipated as a result of enforcing the new rule will be in providing guidance to businesses subject to the franchise tax regarding combined reporting under Tax Code, Chapter 171. This new rule is adopted under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed new rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

This new rule is proposed under Tax Code, §111.002, which provides the Comptroller with the authority to prescribe, adopt, and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

The proposed new section implements Tax Code, §§171.0001, 171.0002, 171.002, 171.101, 171.1011, 171.1014, 171.1016, 171.103, 171.105, 171.1055, and 171.0021.

§3.590. Margin: Combined Reporting.

(a) Effective date. The provisions of this section apply to franchise tax reports originally due on or after January 1, 2008.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Affiliated group--Entities in which a controlling interest is owned by a common owner or owners, either corporate or noncorporate, or by one or more of the member entities.

(2) Combined group--Taxable entities that are part of an affiliated group engaged in a unitary business and that are required to file a combined group report under Tax Code, §171.1014.

(A) A combined group may not include a taxable entity that conducts business outside the United States if 80% or more of the taxable entity's property and payroll are assigned to locations outside the United States. The combined group may not include a taxable entity that conducts business outside the United States and has no property or payroll if 80% or more of the taxable entity's gross receipts are assigned to locations outside the United States. See Tax Code, §171.1014.

(B) A combined group may not include an exempt entity.

(C) A combined group must include eligible entities even if those entities do not have nexus as described in §3.586 of this title (relating to Margin: Nexus).

(D) Pass-through entities (including partnerships), limited liability companies taxed as partnerships under federal law, limited liability companies that are disregarded under federal law, and S corporations must be included in a combined group.

(E) Insurance companies that pay gross premiums tax are not included in a combined group.

(F) Passive entities are not included in the combined group; however, the pro rata share of net income from a passive entity shall be included in total revenue to the extent it was not generated by the margin of another taxable entity.

(3) Combined group report--A report that includes the business of all members of the combined group.

(4) Controlling interest.

(A) Controlling interest means:

(i) for a corporation, either more than 50%, owned directly or indirectly, of the total combined voting power of all classes of stock of the corporation, or more than 50% owned directly or indirectly, of the beneficial ownership interest in the voting stock of the corporation;

(ii) for a partnership, association, trust or other entity other than a limited liability company, more than 50%, owned directly or indirectly, of the capital, profits, or beneficial interest in the partnership, association, trust, or other entity;

(iii) for a limited liability company, either more than 50%, owned directly or indirectly, of the total membership interest of the limited liability company or more than 50%, owned directly or indirectly, of the beneficial ownership interest in the membership interest of the limited liability company.

(B) Examples are as follows:

(i) Corporation A owns 10% of Corporation C and 60% of Corporation B, which owns 41% of Corporation C. Corporation A has a controlling interest in Corporation B and a controlling interest in Corporation C of 51% of stock ownership because it has control of the stock owned by Corporation B.

(ii) Corporation A owns 10% of Limited Liability Company C and 15% of Corporation B, which owns 90% of Limited Liability Company C. Corporation A does not have controlling interest in Limited Liability Company C and does not have a controlling interest in Corporation B. Corporation B has a controlling interest in Limited Liability Company C.

(iii) Individual A owns 100% of 10 corporations, each of which owns 10% of Partnership B. Individual A has a controlling interest in each of the ten corporations and in Partnership B.

(iv) Corporation A holds a 70% interest in Partnership B that owns 60% of Limited Liability Company C. Corporation A owns the remaining 40% of Limited Liability Company C. Corporation A owns a controlling interest in Partnership B and a 100% controlling interest in Limited Liability Company C.

(C) In addition to the foregoing tests, the comptroller may consider any other circumstance that tends to demonstrate that the more than 50% direct or indirect common ownership test was met or was not met.

(D) Membership in an affiliated group shall be treated as terminated in any year, or fraction thereof, in which the conditions listed in this paragraph are not met, except as follows:

(i) when an affiliate is sold, exchanged, or otherwise disposed of, the membership in an affiliated group shall not be terminated if the requirements of this paragraph are again met immediately after the sale, exchange, or disposition.

(ii) The comptroller may treat the affiliated group as remaining in place if the conditions of this paragraph are again met within a period not to exceed two years.

(5) Reporting entity--The combined group's choice of an entity that is the parent entity, if it is part of the unitary business, or the entity that:

(A) is included within the combined group;

(B) is subject to Texas' taxing jurisdiction; and

(C) has the greatest Texas business activity during the first year that a combined report is required to be filed, as measured by the total revenue for that year.

(6) Unitary business--A single economic enterprise that is made up of separate parts of a single entity or of a commonly controlled group of entities that are sufficiently interdependent, integrated, and interrelated through their activities so as to provide a synergy and mutual benefit that produces a sharing or exchange of value among them and a significant flow of value to the separate parts. In determining whether a unitary business exists, the comptroller shall consider any relevant factor, including:

(A) whether:

(i) activities of the group members are in the same general line, such as manufacturing, wholesaling, retailing of tangible personal property, transportation, or finance;

(ii) the activities of the group members are steps in a vertically structured enterprise or process, such as the steps involved in the production of natural resources, including exploration, mining, refining, and marketing; or

(iii) the members are functionally integrated through the exercise of strong centralized management, such as authority over purchasing, financing, product line, personnel, and marketing.

(B) Other factors. In addition, the comptroller may consider other factors that may be applicable, including guidelines in Supreme Court decisions that presume activities are unitary. All affiliated entities are presumed to be engaged in a unitary business.

(C) New entities. When a taxable entity acquires another entity, a presumption exists for finding a unitary relationship during the first reporting period. Any party may rebut such presumption by proving that the taxable entities were not unitary. If such presumption is rebutted, then the taxable entities shall not be considered unitary as of the date of acquisition. When a taxable entity forms another taxable entity, a unitary relationship exists as of the date of formation unless the business is not unitary on a longer term basis.

(D) Non-arm's-length prices. Goods or services or both are supplied at non-arm's length prices between or among entities. Existence of arm's-length pricing between entities, however, does not indicate lack of unity.

(E) Existence of benefits from joint, shared or common activity. A discount, cost-saving or other benefit can be shown to result from joint purchases, leaseholds, or other forms of joint, shared or common activities between or among entities.

(F) Relationships of joint, shared or common activity to income-producing operations. In determining whether a joint, shared, or common activity is indicative of a unitary relationship, consideration shall be given to the nature and character of the basic operations of each entity. Such consideration shall include, but not be limited to, the entity's sources of supply, its goods or services produced or sold, its labor force, and market to determine whether the joint, shared, or common activity is directly beneficial to, related to, or reasonably necessary to the income-producing activities of the unitary business.

(G) Holding entities. The tests for a unitary business established by this section apply in determining whether a holding entity is included or excluded from a unitary business.

(7) United States--The 50 states and the District of Columbia. It also includes the territorial waters of the United States and the seabed and subsoil of those submarine areas that are adjacent to the territorial waters of the United States and over which the United States has exclusive rights, in accordance with international law, with respect to the exploration for or exploitation of natural resources. It also includes the possessions and territories of the United States and the Commonwealth of Puerto Rico.

(c) Mandatory combined reporting. A combined group shall file a combined group report. A taxable entity that is not included in a combined report must file a separate report if it is doing business in Texas or is chartered or organized in Texas.

(d) Determination of combined taxable margin and apportionment.

(1) Combined total revenue. A combined group shall determine its total revenue by:

(A) determining the total revenue of each of its members as provided by Tax Code, §171.1011 (including §171.1011(h)) and §3.587 of this title (relating to Margin: Total Revenue) as if the member were an individual taxable entity without regard to the $300,000 limitation provided by Tax Code, §171.002(d)(2);

(B) adding the total revenues of the members determined under subparagraph (A) of this paragraph, together; and

(C) subtracting, to the extent included under Tax Code, §§171.1011(c)(1)(A), (c)(2)(A), or (c)(3), items of total revenue received from a member of the combined group.

(2) Combined cost of goods sold.

(A) A combined group that elects to subtract costs of goods sold shall determine that amount by:

(i) determining the cost of goods sold for each of its members as provided by Tax Code, §171.1012 and §3.588 of this title (relating to Margin: Cost of Goods Sold) as if the member were an individual taxable entity;

(ii) adding the amounts of cost of goods sold determined under clause (i) of this subparagraph, together; and

(iii) subtracting from the amount determined under clause (ii) of this subparagraph, any cost of goods sold amounts paid from one member of the combined group to another member of the

combined group, but only to the extent the corresponding item of total revenue was subtracted under paragraph (1)(C) of this subsection.

(B) A member of a combined group may claim as cost of goods sold those costs that qualify under Tax Code, §171.1012, if the goods for which the costs are incurred are owned by another member of the combined group.

(3) Combined compensation. The combined group may not subtract in relation to a person, more than $300,000 or the amount determined under Tax Code, §171.006, per 12-month period on which margin is based. A combined group that elects to subtract compensation shall determine that amount by:

(A) determining the compensation for each of its members as provided by Tax Code, §171.1013 and §3.589 of this title (relating to Margin: Compensation), as if each member were an individual taxable entity;

(B) adding the amounts of compensation determined under subparagraph (A) of this paragraph, together; and

(C) subtracting from the amount determined under subparagraph (B) of this paragraph, any compensation amounts paid from one member of the combined group to another member of the combined group, but only to the extent the corresponding item of total revenue was subtracted under paragraph (1)(C) of this subsection.

(4) Combined groups are eligible to elect to use the 70% of revenue calculation pursuant to Tax Code, §171.101 or E-Z Computation pursuant to Tax Code, §171.1016. See §3.584 of this title (relating to Margin: Reports and Payments).

(5) Combined apportionment.

(A) The combined margin is generally apportioned in accordance with §3.591 of this title (relating to Margin: Apportionment).

(B) Except as provided in subparagraph (D) of this paragraph, gross receipts from business done in this state of taxable entities without nexus individually in Texas are excluded from the numerator. For example, sales of tangible personal property shipped into Texas by a member that does not have nexus individually are excluded from the numerator but are included in the denominator.

(C) For each member of the combined group that does not have nexus individually with this state for purpose of taxation, a combined group must, for information purposes only, include in a report filed under Tax Code, §171.201 or §171.202:

(i) the gross receipts computed under subparagraph (B) of this paragraph; and

(ii) the gross receipts computed under subparagraph (B) of this paragraph, that are subject to taxation in another state under a throwback law or regulation.

(D) Receipts derived from transactions between members of a combined group that are excluded under Tax Code, §171.1014(c)(3), may not be included in the numerator or denominator of the apportionment factor. However, the numerator of the apportionment factor will include certain sales of tangible personal property made to third party purchasers if the tangible personal property is ultimately delivered to a purchaser in Texas without substantial modification. See Tax Code, §171.1055(b). For example, drop shipments made from a Texas location to a Texas purchaser would be included in Texas receipts based on the amount billed to the third party purchaser if the seller is a member of the combined group and the seller does not have nexus.

(6) When reporting revenue, cost of goods sold, compensation and gross receipts for a disregarded entity, that information may be included with the parent; in that event, both entities are presumed to have nexus.

(e) Reporting entity.

(1) Responsibilities of the reporting entity.

(A) Access to records. In addition to the information required to be included in the combined group report, upon request of the comptroller, the reporting entity shall provide access to the tax, financial, and nonfinancial records of entities that do and do not have Texas nexus.

(B) Filing. The reporting entity shall file a combined group report on behalf of the combined group together with all reports and schedules required by the comptroller. Any elections required by the combined group are binding on all members of the group.

(C) Payment. The reporting entity shall timely remit to the comptroller the Texas franchise tax imposed on the combined group.

(D) Authority. The reporting entity may file refund claims, give waivers and execute agreements on behalf of the combined group. Any refund claim, waiver given, agreement or any document executed, shall be considered as having also been given or executed by each combined group member.

(2) Notices. Notices mailed to the reporting entity shall be deemed to have been mailed to each of the taxable entities in the combined group.

(3) Change in the reporting entity. The reporting entity shall change only when the entity (other than the parent) is no longer subject to Texas' jurisdiction to tax or the reporting entity is no longer a member of the combined group, at which time the combined group shall designate another entity that qualifies as its reporting entity and notify the comptroller of the designation.

(f) Accounting period of the combined group.

(1) The combined group's accounting period is determined as follows:

(A) if two or more members of a combined group file a federal consolidated return, the group's accounting period is the federal taxable period of the federal consolidated group;

(B) in all other instances, the accounting period is the federal taxable period of the reporting entity.

(2) Members with different accounting periods. If the federal taxable period of a member differs from the federal taxable period of the combined group, the reporting entity will determine the portion of that member's revenue, cost of goods sold, compensation, etc. to be included by preparing a separate income statement prepared from the books and records for the months included in the group's accounting period.

(g) Liability for the combined tax, penalty, and interest. The members of a combined group shall be jointly and severally liable for the combined tax reported on the combined report and any interest and penalty.

(h) Credits. Unless otherwise provided by law, credits generally may be applied against the combined tax liability of the combined group. See §3.594 of this title (relating to Margin: Temporary Credit for Business Loss Carryforwards), and §3.593 of this title (relating to Margin: Credits).

(i) Tax rate. The determination of whether a combined group entity is eligible for a lower tax rate or to file a no tax due report under Tax Code, §§171.002, 171.0021, and 171.1016, shall be made for the combined group as a whole after eliminations. See §3.584 of this title (relating to Reports and Payments).

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 August 28, 2007.

TRD-200703928
Martin Cherry
General Counsel
Comptroller of Public Accounts
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-0387

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34 TAC §3.591

The Comptroller of Public Accounts (Comptroller) proposes new §3.591, concerning Margin: Apportionment. This proposed new section implements House Bill 3, 79th Legislature, Third Called Special Session, 2006, and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This new section establishes guidelines for the apportionment of the franchise tax. Subsection (a) provides that this new section only applies to franchise tax reports originally due on or after January 1, 2008. Subsection (b) defines words and terms used in the new section. Subsection (c) gives the apportionment formula and provides for two exceptions to the apportionment formula. Subsection (d) provides general rules for reporting gross receipts. Subsection (e) provides the treatment of specific items of revenue in the computation of gross receipts. Subsection (f) provides guidance in the determination of gross receipts for natural gas production.

John Heleman, Chief Revenue Estimator, has determined that, for the first five-year period the proposed new rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that, for each year of the first five years the proposed new rule is in effect, the public benefit anticipated as a result of enforcing the new rule will be in providing guidance to businesses subject to the franchise tax regarding the apportionment of margin under Tax Code, Chapter 171. This new rule is proposed under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed new rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

This new rule is proposed under Tax Code, §111.002, which provides the Comptroller with the authority to prescribe, adopt, and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

The proposed new section implements Tax Code, §§171.103, 171.1055, 171.106, and 171.1121.

§3.591. Margin: Apportionment.

(a) Effective date. The provisions of this section apply to franchise tax reports originally due on or after January 1, 2008.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Capital asset--Any asset, other than an investment, that is held for use in the production of income, and that is subject to depreciation, depletion or amortization.

(2) Commercial domicile--The principal place from which the trade or business of the entity is directed.

(3) Employee retirement plan--A plan or other arrangement that qualifies under Internal Revenue Code (IRC), §401(a), or that satisfies the requirement of IRC, §403, or a government plan described in IRC, §414(d).

(4) Gross receipts--The amount determined as total revenue under §3.587 of this title (relating to Margin: Total Revenue), except for a taxable entity taking a deduction for uncompensated care or pro bono services or an entity for which subsection (e)(17) of this section, applies.

(5) Internal Revenue Code--The Internal Revenue Code of 1986 in effect for a specified tax year as provided by Tax Code, §171.0001.

(6) Investment--Any non-cash asset that is not a capital asset.

(7) Legal domicile--The legal domicile of a corporation or limited liability company is its state of formation. The legal domicile of a partnership, trust, or joint venture is the principal place of business of the partnership, trust, or joint venture. The principal place of business of a partnership, trust, or joint venture is the location of its day-to-day operations. If the day-to-day operations are conducted equally or fairly evenly in more than one state, then the principal place of business is the commercial domicile.

(8) Location of payor--The legal domicile of the payor.

(9) Security--An instrument defined under Internal Revenue Code, §475(c)(2), and includes instruments described by §475(e)(2)(B), (C), and (D) of that code.

(10) Tax reporting period--The period upon which the tax is based under Tax Code, §171.1532 or §171.0011.

(11) Taxable entity--Any entity upon which tax is imposed under Tax Code, §171.0002(a) and not specifically excluded under Tax Code, §171.0002(b) or §171.0002(c). See also §3.581 of this title (relating to Taxable and Non-Taxable Entities).

(c) Apportionment formula. A taxable entity's margin is apportioned to this state to determine the amount of franchise tax due by multiplying the taxable entity's margin by a fraction, the numerator of which is the taxable entity's gross receipts from business done in this state and the denominator of which is the taxable entity's gross receipts from its entire business except as provided by this subsection.

(1) Taxable entities that have margin that is derived, directly or indirectly from the sale of services to or on behalf of a regulated investment company as defined by IRC, §851(a), should refer to Tax Code, §171.106(b), relating to the apportionment of gross receipts from services for regulated investment companies.

(2) Taxable entities that have margin that is derived, directly or indirectly, from the sale of management, administration, or investment services to an employee retirement plan, as defined in subsection (b)(3) of this section, should refer to Tax Code, §171.106(c), relating to the apportionment of gross receipts from services for employee retirement plans.

(d) General rules for reporting gross receipts.

(1) A taxable entity that files an annual report must report gross receipts based on the business done by the taxable entity beginning with the day after the date upon which the previous report was based, and ending with the last accounting period ending date for federal income tax purposes ending in the calendar year before the calendar year in which the report is originally due. If the taxable entity has not filed a previous report and must file an annual report, see §3.595 of this title (relating to Margin: Transition Rule).

(2) A taxable entity that files an initial report must report gross receipts based on its activities commencing with the beginning date, as described in §3.584 of this title (relating to Margin: Reports and Payments), and ending on the last accounting period ending date for federal income tax purposes that is at least 60 days before the original due date of the initial report.

(3) Taxable entities that are members of an affiliated group that are part of a unitary business must file a combined franchise tax report. See §3.590 of this title (relating to Margin: Combined Reporting), for determining gross receipts for a combined report.

(4) When a taxable entity computes gross receipts for apportionment, the taxable entity is deemed to have elected to use the same methods that the taxable entity used in filing its federal income tax return.

(5) Any item of revenue that is excluded from total revenue under Texas law or United States law is excluded from gross receipts everywhere and gross receipts in Texas as provided by Tax Code, §171.1055(a). For example, any amount that is excluded from total revenue under the Internal Revenue Code, §78 or §§951 - 964, is excluded from gross receipts.

(6) A taxable entity that uses a 52-53 week accounting year end and that has an accounting year that ends during the first four days of January of the year in which the report is originally due may use the preceding December 31 as the date through which margin is computed.

(7) Any item of allocated revenue excluded under §3.587(c)(9) of this title (relating to Margin: Total Revenue) is excluded from Texas receipts and receipts everywhere.

(e) Treatment of specific items in the computation of gross receipts.

(1) Bad debt recoveries. Bad debt recoveries are gross receipts.

(2) Capital assets and investments. Except as provided by paragraph (17) of this subsection, net gains and losses from sales of investments and capital assets must be added to determine the total gross receipts from such transactions. If both Texas and out-of-state sales have occurred, then a separate calculation of net gains and losses on Texas sales must be made. If the combination of net gains and losses results in a net loss, the taxable entity should net the loss against other receipts, but not below zero. In no instance shall the apportionment factor be greater than 1. Net gain on sales of intangibles held as capital assets or investments is apportioned to the location of the payor. Examples of intangibles include, but are not limited to, stocks, bonds, commodities, futures contracts, patents, copyrights, licenses, trademarks, franchises, goodwill, and general receivable rights.

(3) Computer software services and programs. Gross receipts from the sale of computer software services are apportioned to the location where the services are performed. Gross receipts from the sale of a computer program (as the term "computer program" is defined in §3.308 of this title (relating to Computers - Hardware, Software, Services and Sales)), are receipts from the sale of an intangible asset and are apportioned to the legal domicile of the payor.

(4) Condemnation. Revenues from condemnation that result from the taking of property are gross receipts that are apportioned based on the location of the property condemned.

(5) Debt forgiveness. If a creditor releases any part of a debt, then the amount that the creditor forgives is a gross receipt that is apportioned to the legal domicile of the creditor.

(6) Debt retirement. Revenues from the retirement of a taxable entity's own indebtedness, such as through the taxable entity's purchase of its own bonds at a discount, are gross receipts that are apportioned to the taxable entity's legal domicile. The indebtedness is treated as an investment in the determination of the amount of gross receipts.

(7) Deemed sales of assets under Internal Revenue Code, §338. Amounts that are deemed to have been received by the target taxable entity are treated as sales of assets by the target taxable entity, and are apportioned according to rules that otherwise apply to sales of such assets under Tax Code, Chapter 171, or this section. For the purposes of this paragraph, the purchaser of the target's stock is considered the purchaser of the assets.

(8) Dividends and/or interest.

(A) Dividends that are recognized as a reduction of the taxpayer's basis in stock of a taxable entity for federal income tax purposes are not gross receipts. Dividends that exceed the taxpayer's basis for federal income tax purposes that are recognized as a capital gain are treated as dividends for apportionment purposes.

(B) The following are excluded from Texas receipts and receipts everywhere:

(i) dividends from a subsidiary, associate, or affiliated taxable entity that does not transact a substantial portion of its business or regularly maintain a substantial portion of its assets in the United States;

(ii) schedule C special deductions that are excluded from total revenue;

(iii) dividends and/or interest on federal obligations that are excluded from total revenue;

(iv) interest that is exempt from federal income tax.

(C) Dividends and/or interest that are received from a corporation or other sources are apportioned to the legal domicile of the payor.

(D) Dividends and/or interest that are received from a national bank are apportioned to Texas if the bank's principal place of business is located in Texas. Dividends and/or interest that are received from a bank that is organized under the Texas Banking Code are apportioned to Texas.

(E) A banking corporation may exclude from its Texas gross receipts interest that is earned on federal funds and interest that is earned on securities that are sold under an agreement to repurchase and that are held in a correspondent bank that is domiciled in Texas, but the banking corporation must include the interest in its gross receipts everywhere.

(9) Exchanges of property. Exchanges of property are included in gross receipts to the extent that the exchange is recognized as a taxable transaction for federal income tax purposes. Such exchange must be included in receipts based on the gross exchange value, unless otherwise required under this section.

(10) Federal enclave. All revenues from a taxable entity's sales, services, leases, or other business activities that are transacted on a federal enclave that is located in Texas are Texas receipts, unless otherwise excepted by this section.

(11) Insurance proceeds.

(A) Business interruption insurance proceeds are gross receipts when the proceeds are intended to replace lost profits. Such receipts are apportioned to the legal domicile of the payor of the proceeds.

(B) Revenues from fire and casualty insurance proceeds are apportioned to the location of the damaged or destroyed property.

(12) Internet access fee. A fee that is charged to obtain access to the World Wide Web in Texas is a Texas gross receipt.

(13) Leases and subleases.

(A) Revenues from the lease or sublease (or rental or subrental) of real property are apportioned to the location of the property.

(B) Revenues from the lease or sublease (or rental or subrental) of tangible personal property are apportioned to the location of the property. If the property is used both inside and outside Texas, then lease payments are apportioned based on the number of days that the tangible personal property was used in Texas divided by the number of days that the tangible personal property was used everywhere. If the amount of revenue that is due under the lease is based on mileage, then the lease payments are apportioned based on the number of miles in Texas divided by the number of miles everywhere.

(C) If a lump sum is charged for leased or subleased (or rented or subrented) property that is located both inside and outside Texas, then the allocation of such revenue is based on the rental value of each item of property.

(D) Revenues from the lease or sublease (or rental or subrental) of a vessel that engages in commerce are apportioned to Texas based on the number of days that the vessel is engaged in commerce in Texas waters divided by the number of days that the vessel is engaged in commerce everywhere.

(E) If a lease, sublease, rental, or subrental of real property or tangible personal property is treated as a sale for federal income tax purposes, then the receipts from the transaction are apportioned in the same manner as a sale. Any portion of the payments that the contracting parties designate as interest is interest receipts.

(14) Litigation awards. Revenues that are realized from litigation awards are gross receipts that are apportioned to the legal domicile of the payor of the proceeds; however, if the litigation awards are intended to replace receipts for which another apportionment rule is provided in this section, then the apportionment must be made in accordance with that rule. For example, if a taxable entity sues a Delaware corporation to recover on a sale of goods delivered to a Texas location, then a judgment for the amount of that sale would not convert the receipts from Texas receipts to Delaware receipts. See subsection (f) of this section, for the apportionment of receipts from judgments, compromises, or settlements that relate to natural gas production.

(15) Loan servicing of real property. Receipts from the servicing of loans secured by real property are apportioned to the location of the collateral real property that secures the loan being serviced.

(16) Loans and securities. If a loan or security is treated as inventory of the seller for federal income tax purposes, the gross proceeds of the sale of that loan or security are considered gross receipts.

(17) Membership or enrollment fees paid for access to benefits. Membership or enrollment fees paid for access to benefits should be considered gross receipts from the sale of an intangible asset and are apportioned to the legal domicile of the payor.

(18) Mixed transactions. If a transaction involves elements of both a sale of tangible personal property and a service, but no documentation exists to show separate charges for the sale and service elements, then the comptroller may determine the amounts that are allocable to each element based on fair values or on any available evidence.

(19) Net distributive income. The net distributive income from a passive entity that is included in total revenue is apportioned to the principal place of business of the passive entity.

(20) Newspapers or magazines. All advertising revenues of a newspaper or magazine, including those revenues derived from out-of-state advertisements, are apportioned to Texas based on the number of newspapers or magazines distributed in Texas. All other receipts must be apportioned in accordance with the apportionment rules otherwise set out in this section. For example, receipts from sales of newspapers or magazines are to be apportioned based on paragraph (30) of this subsection.

(21) Patents, copyrights, and other intangible rights.

(A) Receipts from the use of intangibles.

(i) Revenues from a patent royalty are included in Texas receipts to the extent that the patent is utilized in production, fabrication, manufacturing, or other processing in Texas.

(ii) Revenues from a copyright royalty are included in Texas receipts to the extent that the copyright is utilized in printing or other publication in Texas.

(iii) Revenues that the owner of a trademark, franchise, or license receives are included as Texas receipts to the extent the trademark, franchise or license is used in Texas.

(iv) Royalties from an affiliated taxable entity that does not transact a substantial portion of its business or regularly maintain a substantial portion of its assets in the United States are excluded from Texas receipts and receipts everywhere.

(B) Sales. Sales of intangibles are apportioned based on the location of payor.

(22) Radio/television. All advertising revenues of a radio or television station that broadcasts or transmits from a location in Texas constitute Texas receipts, even though some of the listening or viewing audiences are located outside Texas. All other receipts must be apportioned in accordance with the apportionment rules otherwise set out in this section.

(23) Real property. Revenues from the sale, lease, rental, sublease, or subrental of real property, including mineral interests, are apportioned to the location of the property. Royalties from mineral interests are considered revenue from real property.

(24) Sales taxes. State or local sales taxes that are imposed on the customer, but are collected by a seller are not gross receipts of the seller. However, discounts that a seller is allowed to take in remittance of the collected sales tax are gross receipts to the seller.

(25) Securities. Receipts from the sale of securities are apportioned based on the location of the payor. If securities are sold through an exchange, and the buyer cannot be identified, then 7.9% of the revenue is a Texas receipt.

(26) Services. Receipts from a service are apportioned to the location where the service is performed. If services are performed

both inside and outside Texas, then such receipts are Texas receipts on the basis of the fair value of the services that are rendered in Texas.

(A) Taxable entities that have margin that is derived, directly or indirectly, from the sale of services to or on behalf of a regulated investment company should refer to Tax Code, §171.106(b), for information on apportionment of such margin.

(B) Taxable entities that have margin that is derived, directly or indirectly, from the sale of management, administration, or investment services to an employee retirement plan as defined in subsection (b)(3) of this section, should refer to the Tax Code, §171.106(c), for information on apportionment of such margin.

(C) Receipts from services that a defense readjustment project performs in a defense economic readjustment zone are not Texas receipts.

(27) Services procurement. Revenues for the procurement of services are apportioned to the place where the service procurement is performed.

(28) Subsidies or grants. Proceeds of subsidies or grants that a taxable entity receives from a governmental agency are gross receipts, except when the funds are required to be expended dollar-for-dollar (i.e., passed through) to third parties on behalf of the agency. Receipts from a governmental subsidy or grant are apportioned in the same manner as the item to which the subsidy or grant was attributed. For example, if a taxable entity qualifies for a grant to conduct research for the government, then the receipts from that grant are receipts from a service and are apportioned to the location where the research is performed.

(29) Tangible personal property. Examples of transactions that involve the sale of tangible personal property and result in Texas receipts include, but are not limited to, the following:

(A) the sale of tangible personal property that is delivered in Texas to a purchaser. Delivery is complete upon transfer of possession or control of the property to the purchaser, an employee of the purchaser, or transportation vehicles that the purchaser leases or owns. FOB point, location of title passage, and other conditions of the sale are not relevant to the determination of Texas gross receipts;

(B) the sale of tangible personal property that is delivered in Texas to an employee or transportation agent of an out-of-state purchaser. A carrier is an employee or agent of the purchaser if the carrier is under the supervision and control of the purchaser with respect to the manner in which goods are transported;

(C) the sale and delivery in Texas of tangible personal property that is loaded into a barge, truck, airplane, vessel, tanker, or any other means of conveyance that the purchaser of the property leases and controls or owns. The sale of tangible personal property that is delivered in Texas to an independent contract carrier, common carrier, or freight forwarder that a purchaser of the property hires results only in gross receipts everywhere if the carrier transports or forwards the property to the purchaser outside this state;

(D) the sale of tangible personal property with delivery to a common carrier outside Texas, and shipment by that common carrier to a purchaser in Texas;

(E) the sale of oil or gas to an interstate pipeline company, with delivery in Texas;

(F) the sale of tangible personal property that is delivered in Texas to a warehouse or other storage facility that the purchaser owns or leases;

(G) the sale of tangible personal property that is delivered to and stored in a warehouse or other storage facility in Texas at the purchaser's request, as opposed to a necessary delay in transit, even though the property is subsequently shipped outside Texas;

(H) the drop shipment of tangible personal property in Texas. A drop shipment is a shipment of tangible personal property from a seller directly to a purchaser's customer, at the request of the purchaser, without passing through the hands of the purchaser. This results in Texas gross receipts for the seller and the purchaser;

(30) Telephone companies.

(A) Revenues from telephone calls that both originate and terminate in Texas are Texas receipts.

(B) Revenues from telephone calls that originate in Texas but terminate outside of Texas or that originate outside of Texas but terminate in Texas are excluded from Texas receipts.

(C) Revenues from telecommunication services other than those services in subparagraph (A) or (B) of this paragraph are Texas receipts if the services are performed in Texas. For example, a telephone company that provides a long distance carrier access to the telephone company's local exchange network in Texas is performing a service in Texas. Any fee that the telephone company charges the long distance carrier for access to the local exchange network in Texas is a Texas receipt regardless of whether the access is related to an interstate call. A fee that is charged to obtain access to a local exchange network in Texas and that is based on the duration of an interstate telephone call may be excluded from Texas receipts.

(31) Texas waters. Revenues from transactions that occur in Texas waters are Texas receipts. Texas waters are considered to extend to 10.359 statute miles, or nine nautical miles, from the Texas coastline.

(32) Transportation companies. Transportation companies must report Texas receipts from transportation services in intrastate commerce by:

(A) the inclusion of revenues that are derived from the transportation of goods or passengers in intrastate commerce within Texas; or

(B) the multiplication of total transportation receipts by total mileage in the transportation of goods and passengers that move in intrastate commerce within Texas divided by total mileage everywhere.

(f) Natural gas production.

(1) Revenues that a gas producer realizes from the contract price of gas that the gas producer produces and that the purchaser takes pursuant to the terms of sales are gross receipts and are apportioned to Texas, if the gas is delivered in Texas.

(2) Revenues that a gas producer realizes from a purchaser's payment under a sale or purchase contract for gas to be produced even if no gas is produced and delivered to the purchaser, are gross receipts and are apportioned to the legal domicile of the payor.

(3) Revenues that a gas producer realizes from a purchaser's payments to terminate a gas purchase contract are gross receipts and are apportioned to the legal domicile of the payor.

(4) Revenues that a gas producer realizes from a contract amendment that relates to the price of the gas sold are gross receipts from the sales of gas and are apportioned to Texas if delivery is made to a location in Texas. Revenues that the gas producer realizes from a contract amendment that relates to a provision other than the price of

gas sold are gross receipts and are apportioned to the legal domicile of the payor.

(5) Revenues that a gas producer realizes from litigation awards for a breach of contract, reimbursements for litigation-related expenses (e.g., documented attorney's fees or court costs), or interest (upon which the parties have agreed, that the records of the producer reflects, or in an amount that a court has ordered) are gross receipts and are apportioned to the legal domicile of the payor.

(6) Revenues that a gas producer realizes from a judgment, compromise, or settlement relating to the recovery of a contract price of gas produced are gross receipts and are apportioned to Texas to the extent the contract specified delivery to a location in Texas. Revenues that a gas producer realizes from a judgment, compromise, or settlement that relates to several claims or causes of action shall be prorated based upon the documented amounts due under the contract for each claim or cause of action according to the records of the producer. For example, a settlement sum of $100,000 for a pricing dispute of $25,000 and for failure to pay for gas not taken in the amount of $225,000, would result in receipts of $10,000 from gas sales (100,000 X 25,000/250,000) and receipts from other business of $90,000 (100,000 X 225,000/250,000). Records of the producer shall include, but are not limited to the following: contracts, settlement agreements, accounting records and entries, court pleadings and worksheets, including calculations reflecting settlement amounts.

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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Martin Cherry
General Counsel
Comptroller of Public Accounts
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For further information, please call: (512) 475-0387

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34 TAC §3.592

The Comptroller of Public Accounts proposes new §3.592, concerning margin: additional tax. This section implements House Bill 3, 79th Legislature, Third Called Session 2006 and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This section establishes guidelines for computing additional tax under Tax Code, Chapter 171. Subsection (a) provides the effective date. Subsection (b) provides the due date. Subsection (c) provides the tax rate and period upon which the additional tax is based. Subsections (d) and (e) refer to other sections for more information.

John Heleman, Chief Revenue Estimator, has determined that for the first five-year period the rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that for each year of the first five years the rule is in effect, the public benefit anticipated as a result of enforcing the rule will be in providing guidance to taxable entities which no longer have sufficient nexus with Texas to be subject to the franchise tax for computing and remitting additional tax under Tax Code, Chapter 171. This rule is adopted under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

This rule is proposed under Tax Code, §111.002, which provides the comptroller with the authority to prescribe, adopt, and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

The new section implements Tax Code, §171.0011.

§3.592. Margin: Additional Tax.

(a) Effective date. For reports originally due on or after January 1, 2008, the additional tax imposed by Tax Code, §171.0011, applies to a taxable entity which no longer has sufficient nexus with Texas to be subject to the franchise tax. All provisions of Tax Code, Chapter 171, apply to the additional tax, unless they conflict with a provision in Tax Code, §171.0011.

(b) Due date. A final report and payment of the additional tax are due within 60 days after the taxable entity no longer has sufficient nexus with Texas to be subject to the franchise tax. However, an estimated return and payment may need to be filed and paid before a taxable entity will receive clearance from the comptroller to terminate, dissolve, merge, or withdraw. As long as the proper amount is paid and an amended return, if needed, is filed within 60 days after the taxable entity terminates, dissolves, merges, or withdraws, then no penalty or interest will be assessed.

(c) Rate and business based on. The additional tax rate is determined by Tax Code, §171.002 and is applied to taxable margin for the period from the day after the last day for which tax under Tax Code, Chapter 171, was based on a previous report through the date the taxable entity no longer has sufficient nexus with Texas to be subject to the franchise tax.

(d) Passive entities. See §3.582 of this title (relating to Margin: Passive Entities).

(e) Combined reports. See §3.590 of this title (relating to Margin: Combined Reporting).

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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34 TAC §3.593

The Comptroller of Public Accounts proposes new §3.593, concerning margin: franchise tax credits. This section implements House Bill 3, 79th Legislature, Third Called Special Session, 2006 and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This section establishes guidelines for the computation of franchise tax credits under Tax Code, Chapter 171. Subsection (a) provides that this section only applies to franchise tax reports originally due on or after January 1, 2008.

Subsection (b) defines words and terms used in the section. Subsection (c) details the requirement that a credit schedule must be filed. Subsection (d) details the tax limitations for the credits. Subsection (e) details the carryforward and report limitation for the research and development credit. Subsection (f) details the carryforward and report limitation for the jobs creation credit. Subsection (g) details the installment, carryforward and report limitation for the investment credit. Subsection (h) relates to an investment credit for certain enterprise projects and details the calculation of the credit and the limitations.

John Heleman, Chief Revenue Estimator, has determined that for the first five-year period the rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that for each year of the first five years the rule is in effect, the public benefit anticipated as a result of enforcing the rule will be in providing guidance to businesses subject to the franchise tax regarding the computation of franchise tax credits under Tax Code, Chapter 171. This rule is adopted under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

This rule is proposed under Tax Code, §111.002, which provides the comptroller with the authority to prescribe, adopt, and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

The new section implements Tax Code, Chapter 171, Subchapter Q-1.

§3.593. Margin: Franchise Tax Credits.

(a) Effective date. The provisions of this section apply to franchise tax reports originally due on or after January 1, 2008.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise

(1) Research and development credit--A research and development credit established under Tax Code, Chapter 171, Subchapter O, on a franchise tax report originally due prior to January 1, 2008.

(2) Jobs creation credit--A jobs creation credit established under Tax Code, Chapter 171, Subchapter P, on a franchise tax report originally due prior to January 1, 2008.

(3) Investment credit--An investment credit established under Tax Code, Chapter 171, Subchapter Q, on a franchise tax report originally due prior to January 1, 2008 and an investment credit established under Tax Code, Chapter 171, Subchapter Q-1.

(4) Enterprise project--A person designated as an enterprise project under Government Code, Chapter 2303, on or after September 1, 2001, but before January 1, 2005.

(5) Enterprise zone--An area designated as an enterprise zone under Government Code, §2303.003.

(6) Qualified business--A person certified as a qualified business under Government Code, §2303.402.

(7) Qualified capital investment--Tangible personal property that is first placed in service in an enterprise zone by a qualified business that has been designated as an enterprise project and that is defined in IRS Reg. §1.48-1(c) and described in Internal Revenue Code, §1245(a), subject to depreciation or amortization including engines, machinery, tools, and implements that are used in a trade or business, or are held for investment. The term includes transportation costs and direct labor costs necessary to fabricate, install or place the tangible personal property in service. The term does not include real property or buildings and their structural components. Property that is leased under a capitalized lease is considered a "qualified capital investment," but property that is leased under an operating lease is not considered a "qualified capital investment." Property that is expensed under Internal Revenue Code, §179, is not considered a "qualified capital investment." The term also does not include all costs included in the depreciable basis such as indirect labor costs, interest, intangibles and overhead.

(8) Tangible personal property first placed in service in an enterprise zone includes tangible personal property that is:

(A) purchased by an enterprise project for placement in an incomplete improvement that is under active construction or other physical preparation;

(B) identified by a purchase order, invoice, billing, sales slip, or contract; and

(C) physically present at the enterprise project's qualified business site, as defined by Government Code, §2303.003, and in use by the enterprise project on the original due date of the report on which the credit is taken.

(c) Information required. A taxable entity that claims a credit under this section must submit a credit schedule with each report that a credit is claimed.

(d) Limitations.

(1) The total research and development credit, jobs creation and investment credits that a taxable entity claims may not exceed the amount of franchise tax due for the report after any other applicable credits.

(2) A taxable entity may not convey, assign, or transfer to another entity the credits that this section provides, unless all of the assets of the taxable entity are conveyed, assigned, or transferred to the entity in the same transaction.

(e) Research and development credit.

(1) Carryforward. If a taxable entity established a research and development credit on a franchise tax report originally due prior to January 1, 2008, that exceeded the tax limitations, then the taxable entity may continue to carry the unused credit forward on each consecutive report until the earlier of the date the credit would have expired under Tax Code, Chapter 171, Subchapter O, or December 31, 2027.

(2) Report limitation. The total research and development credit carryforward that a taxable entity may claim for a report may not exceed 50% of the amount of franchise tax that is due for the report before any other tax credits are applied.

(f) Jobs creation credit.

(1) Carryforward. If a taxable entity established a jobs creation credit on a franchise tax report originally due prior to January 1, 2008, that exceeded the tax limitations, then the taxable entity may continue to carry the unused credit forward on each consecutive report until the earlier of the date the credit would have expired under Tax Code, Chapter 171, Subchapter P, or December 31, 2012.

(2) Report limitation. The total jobs creation credit carryforward that a taxable entity may claim for a report may not exceed

50% of the amount of franchise tax that is due for the report before any other tax credits are applied.

(g) Investment credit.

(1) Installment. A taxable entity that has any unused installments from an investment credit established on a franchise tax report originally due prior to January 1, 2008, may claim the remaining installments on consecutive reports beginning with reports originally due on or after January 1, 2008.

(2) Carryforward. A carryforward is the remaining portion of an installment that cannot be claimed in the current year because of the limitations that are stated in subsection (d)(1) of this section or this paragraph. A carryforward is added to the next year's installment of the credit in determination of the limitations for that year. A credit carryforward from a previous report must be used before the current year installment. The taxable entity may carry the unused credit forward on each consecutive report until the earlier of the date the credit would have expired under Tax Code, Chapter 171, Subchapter Q, or December 31, 2012.

(3) Report limitation. The total investment credit that a taxable entity may claim for a report including any credit under subsection (h) of this section, may not exceed 50% of the amount of franchise tax that is due for the report before any other tax credits are applied.

(4) Ineligibility.

(A) A taxable entity may not take any remaining installment of the credit, (except the taxable entity is permitted to take the portion of an installment that accrued in a previous year and was carried forward pursuant to paragraph (2) of this subsection), if, during one of the periods used to determine margin for a report on which an installment could be claimed, the taxable entity:

(i) disposes of the qualified capital investment;

(ii) takes the qualified capital investment out of service;

(iii) moves the qualified capital investment out of Texas; or

(iv) fails to pay an average weekly wage, at the location for which the credit is claimed, that amounts to at least 110% of the county average weekly wage.

(B) For purposes of subparagraph (A)(i) - (iii) of this paragraph, an installment may still be taken if the qualified capital investment is replaced at the same location within 90 days with a new qualified capital investment of equal or greater value.

(h) Enterprise projects. A taxable entity that has been designated an enterprise project on or after September 1, 2001, but before January 1, 2005, may establish a credit that equals 7.5% of the qualified capital investment made on or after January 1, 2005, and before January 1, 2007. Subject to paragraph (4) of this subsection, an enterprise project may claim the entire credit established on a report originally due on or after January 1, 2008, and before January 1, 2009.

(1) Carryforward. If an enterprise project is eligible for a credit that exceeds the limitation under paragraph (4) of this subsection, the enterprise project may carry the unused credit forward for not more than five consecutive reports.

(2) Ineligibility.

(A) An enterprise project is not eligible for a credit under this subsection if the enterprise project claimed a credit under Tax Code, Chapter 171, Subchapter Q, before the repeal of that subchapter on January 1, 2008.

(B) A taxable entity, other than a combined group, may not claim the credit under this subsection unless the taxable entity was, on May 1, 2006, subject to the tax imposed by this chapter as it existed on that date.

(C) A taxable entity that establishes its eligibility for an investment credit is not eligible to claim a franchise tax reduction that is authorized under Tax Code, §171.1015.

(3) Combined group. A taxable entity that is a combined group may claim the credit for each member entity that was, on May 1, 2006, subject to the tax imposed by this chapter as it existed on that date and shall compute the amount of the credit for that member as provided by this subsection.

(4) Report limitation. The total investment credit that a taxable entity claims for a report, including the amount of any installment or carryforward under subsection (g)(1) and (g)(2), of this section, may not exceed 50% of the amount of franchise tax that is due for the report before any other tax credits are applied.

(5) Expiration. This subsection expires on December 31, 2009. This expiration does not affect the carryforward of a credit that was established on a report that was originally due before this expiration date.

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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Martin Cherry
General Counsel
Comptroller of Public Accounts
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34 TAC §3.594

The Comptroller of Public Accounts proposes an amendment to §3.594, concerning margin: temporary credit for business loss carryforwards. This section is being amended to implement House Bill 3, 79th Legislature, Third Called Session 2006 and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This amendment establishes guidelines for calculating the temporary credit. Subsection (a) provides that this section only applies to franchise tax reports due on or after January 1, 2008. Subsection (b) defines words and terms used in the section. Subsection (c) outlines the entities eligible to take this credit. Subsection (d) provides notice requirements. Subsection (e) provides for the election of the credit. Subsection (f) describes the calculation of the credit. Tax Code, §171.111(a) was amended to change the preservation date from September 1, 2007 to May 15, 2008. This amendment is found in new subsection (d)(1) of this proposed section.

John Heleman, Chief Revenue Estimator, has determined that for the first five-year period the rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that for each year of the first five years the rule is in effect, the public benefit anticipated as a result of enforcing the rule will be in providing guidance to businesses subject to the franchise tax regarding the temporary

credit for business loss carryforwards under Tax Code, Chapter 171. This rule is adopted under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

This rule is proposed under Tax Code §111.002, which provides the comptroller with the authority to prescribe, adopt, and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

The amendment implements Tax Code, §171.111.

§3.594. Margin: Temporary Credit for Business Loss Carryforwards.

(a) Provisions [~~Effective Date~~]. The provisions of this section apply to franchise tax reports originally due on or after January 1, 2008.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Business loss--Any negative amount of earned surplus after apportionment and allocation but before any deductions for solar energy devices under Tax Code, §171.107, clean coal project under Tax Code, §171.108, or investment in an enterprise zone under Tax Code, §171.1015. Business losses must have been used to offset any positive amount of earned surplus even in years when no tax was due.

(2) Business loss carryforward--Unused and unexpired amounts of business losses created on the 2003 and subsequent franchise tax report years.

(c) Eligibility.

(1) A taxable entity may claim the credit if the entity was, on May 1, 2006, subject to franchise tax.

(2) A taxable entity that is a combined group may claim the credit for each member entity that was, on May 1, 2006, subject to the franchise tax and shall compute the amount of the credit for that member as provided by this section.

(3) If a member of a combined group changes combined groups after June 30, 2007, the business loss carryforward of that member will no longer be included in the temporary credit calculation of the group and the related share of any temporary credit carried over from a previous year is lost to the group. There is no proration for a partial year. In addition, the business loss carryforward does not follow the member to a separately filed report or another combined group. If a member merges into another member of the group, that member's business loss carryforward will remain with the group. If the member dissolves, terminates, or otherwise leaves the group, the business loss carryover of that member is no longer eligible for use.

(4) Example. Corporation A, corporation B, corporation C and corporation D are members of a combined group. They have business loss carryforwards of $2,000,000, $2,000,000, $2,000,000, and $4,000,000 respectively. In 2008, the combined group's credit will be $10,000,000 x 2.25% x 4.5% equaling $10,125. The combined group's tax due before the credit is $9,000 which results in a carryover of $1,025. During 2008, corporation D leaves the group. On the 2009 report, the combined group is entitled to a credit of $6,000,000 x 2.25% x 4.5% equaling $5,075. In addition, the group only has $615 of the carryover credit. They lost the 40% that was related to corporation D. However, if corporation D had merged into corporation C during 2008 instead of leaving the group, the combined group's credit will remain $10,125 for 2009 and there will still be a $1,025 carryover from 2008.

(5) The preservation of the right to claim the credit may not be conveyed, assigned, or transferred to another entity.

(d) [~~(b)~~] Notice requirements[~~of intent~~].

(1) A[~~The~~] notice of intent to preserve the right to claim the temporary credit for business loss carryforwards must be submitted to the comptroller on or before May 15, 2008, on a form prescribed by the comptroller. The postmark date (or meter-mark date, if there is no postmark) on the envelope in which the form is received determines the date of filing [~~under Tax Code, §171.111, must be submitted to the comptroller on forms specified by the comptroller. The form must be filed on or before September 1, 2007. The postmark date (or meter-mark date, if there is no postmark) on the envelope in which the form is received determines the date of filing. The preservation of the right to claim the credit may not be conveyed, assigned, or transferred to another entity~~].

(2) The taxable entity must submit with the notice of intent the amount of business loss that is being carried forward.

(3) If the amount of business loss carryforwards changes after the initial preservation, the entity must notify the comptroller in writing of the change. The notice must be received on or before the original due date of an annual report on which the credit will be used and must include the corrected amount of the eligible business loss carryforwards.

(4) If, upon audit by the comptroller, an adjustment is made to the business loss carryforward used on reports prior to 2008, then no notice is required and the amount of business loss carryforwards that were preserved and subsequently taken will be adjusted accordingly. The taxable entity will be liable for any additional tax, penalty, and interest due for years in which the credit was improperly claimed.

(e) Electing the credit. The election to claim the credit shall be made on each report originally due on or after January 1, 2008 and before September 1, 2027.

(1) A taxable entity elects the credit by:

(A) properly taking the credit on a report filed on or before the original due date; or

(B) electing the credit on a timely filed extension request and properly taking the credit on the report filed on or before the extended due date of the report.

(2) If an election to take the credit is not made on or before the original due date of the report as indicated in paragraph (1) of this subsection, the credit for that year is lost for that year and cannot be carried over to a subsequent year.

(3) A taxable entity that uses the E-Z Computation to report and pay its franchise tax may not elect to take the business loss carryforward credit in that year. The unused credit may not be carried over to subsequent years.

(f) Computation of the credit.

(1) For report years 2008 - 2017: Business loss carryforward amount x 2.25% x 4.5%.

(2) For report years 2018 - 2027: Business loss carryforward amount x 7.75% x 4.5%.

(g) Credit carryover. The amount of credit claimed on any report may not exceed the amount of franchise tax due for that report

year. Unused credits may be carried over to subsequent report years unless subsection (e)(2) of this section applies.

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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General Counsel
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34 TAC §3.595

The Comptroller of Public Accounts proposes new §3.595, concerning margin: transition. This section implements House Bill 3, 79th Legislature, Third Called Session, 2006 and House Bill 3928, 80th Legislature, 2007, which revise the franchise tax. This section establishes guidelines for computing tax liability during the transition period under Tax Code, Chapter 171. Subsection (a) states the effective date is as provided in the section. Subsection (b) provides guidance to entities previously subject to the franchise tax (e.g. corporations and limited liability companies, etc.). Subsection (c) provides guidance to newly taxable entities (e.g. limited partnerships, professional associations, etc.).

John Heleman, Chief Revenue Estimator, has determined that for the first five-year period the rule will be in effect, there will be no significant revenue impact on the state or units of local government.

Mr. Heleman also has determined that for each year of the first five years the rule is in effect, the public benefit anticipated as a result of enforcing the rule will be in providing guidance to businesses subject to the franchise tax regarding the computation of franchise tax during the transition period under Tax Code, Chapter 171. This rule is adopted under Tax Code, Title 2, and does not require a statement of fiscal implications for small businesses. There is no significant anticipated economic cost to individuals who are required to comply with the proposed rule.

Comments on the proposal may be submitted to Bryant K. Lomax, Manager, Tax Policy Division, P.O. Box 13528, Austin, Texas 78711.

This rule is proposed under Tax Code, §111.002, which provides the comptroller with the authority to prescribe, adopt, and enforce rules relating to the administration and enforcement of the provisions of Tax Code, Title 2.

The new section implements House Bill 3, 79th Legislature, Third Called Session, 2006, Section 22 and House Bill 3928, 80th Legislature, 2007, Section 35.

§3.595. Margin: Transition.

(a) Effective date. The provisions of this section apply as provided in this section.

(b) Types of entities previously subject to franchise tax. If an entity is a type of entity that would have been subject to the franchise tax immediately before the passage of House Bill 3, 79th Legislature, 3rd Called Session, 2006, then the margin calculation, as opposed to the taxable capital and earned surplus calculations, should be used for reports originally due on or after January 1, 2008. If an entity is part of a combined group, then the entity will be included in a combined report due in 2008, even if the entity becomes no longer subject to the franchise tax in 2007.

(1) Unless the entity is part of a combined group, if an initial report is due in 2008 or later and the entity becomes no longer subject to the franchise tax on or before November 1, 2007, then the initial report based on margin will be based on the beginning date through the date the entity became no longer subject to the franchise tax and no final report will be due.

(2) If an entity was required to file a report based on earned surplus, then the first report due based on margin should be based on a period beginning on the day after the last date used to calculate earned surplus.

(3) If an entity filed a report based on taxable capital, but was not subject to the earned surplus component, then the first report due based on margin should be based on a period beginning on the day after the last date used to calculate taxable capital.

(4) Except as provided in paragraph (1) of this subsection, if the entity becomes no longer subject to the earned surplus component of the tax on or before November 1, 2007, then the entity will owe a final report based on taxable earned surplus, unless the entity is part of a combined group.

(c) Types of entities becoming subject to the franchise tax under House Bill 3, 79th Legislature, 3rd Called Session, 2006.

(1) Margin or gross receipts occurring before June 1, 2006, may not be considered for purposes of determining taxable margin or for apportionment purposes.

(2) Extensions for 2008 annual reports will not be granted based on 100% of the tax reported as due in the previous calendar year, including combined reports which include at least one entity becoming subject to the franchise tax under House Bill 3, 79th Legislature, 3rd Called Session, 2006.

(3) If the entity becomes no longer subject to the franchise tax before July 1, 2007, then it will not owe franchise tax and the entity will not be included in a combined report. The entity may become "no longer subject to the franchise tax" by terminating its existence. A dissolution, merger out of existence or liquidation is considered a termination. A conversion is not considered a termination. A partnership is considered terminated only if no part of any business, financial operation, or venture of the partnership continues to be carried on by any of its partners in a partnership. For a merger or consolidation of two or more partnerships, the resulting partnership is considered the continuation of any merging or consolidating partnership whose members own an interest of more than 50% in the capital and profits of the resulting partnership. For a division of a partnership into two or more partnerships, the resulting partnerships, other than any resulting partnership the members of which had an interest of 50% or less in the capital and profits of the prior partnership, are considered a continuation of the prior partnership.

(4) An entity doing business in this state at any time after June 30, 2007, and before January 1, 2008, but not on January 1, 2008, shall file a final report based on margin as provided in subsection (b)(2) of this section, of Section 35 of House Bill 3928, 80th Legislature, 2007. The final report is due on the 60th day after the date the entity becomes no longer subject to the franchise tax. The entity will not be included in a combined report.

(5) An entity subject to the franchise tax on January 1, 2008, for which January 1, 2008, is not the beginning date, shall file an annual report due May 15, 2008, based on the period or periods:

(A) if the entity has an accounting period that ends on or after January 1, 2007, and before June 1, 2007:

(i) beginning the later of:

(I) June 1, 2006; or

(II) the date the entity was organized in this state or, if a foreign entity, the date it began doing business in this state; and

(ii) ending on the date that accounting period ends in 2007;

(B) if the entity has an accounting period that ends on or after June 1, 2007, and before December 31, 2007:

(i) beginning on the date that accounting period begins; and

(ii) ending on the date that accounting period ends in 2007; and

(C) if the entity has an accounting period that ends on December 31, 2007, or if the entity does not have an accounting period that ends in 2007:

(i) beginning the later of:

(I) January 1, 2007; or

(II) the date the entity was organized in this state or, if a foreign entity, the date it began doing business in this state; and

(ii) ending on December 31, 2007.

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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Comptroller of Public Accounts
Earliest possible date of adoption: October 14, 2007
For further information, please call: (512) 475-0387

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TITLE 40. SOCIAL SERVICES AND ASSISTANCE

PART 20. TEXAS WORKFORCE COMMISSION

CHAPTER 801. LOCAL WORKFORCE DEVELOPMENT BOARDS

SUBCHAPTER B. ONE-STOP SERVICE DELIVERY NETWORK

40 TAC §801.33

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

The Texas Workforce Commission (Commission) proposes the repeal of the following section of Chapter 801 relating to Local Workforce Development Boards:

Subchapter B. One-Stop Service Delivery Network, §801.33

PART I. PURPOSE, BACKGROUND, AND AUTHORITY

PART II. EXPLANATION OF INDIVIDUAL PROVISIONS

PART III. IMPACT STATEMENTS

PART IV. COORDINATION ACTIVITIES

PART I. PURPOSE, BACKGROUND, AND AUTHORITY

The purpose of this amendment is to remove §801.33 relating to Advertising. This rule change implements the statutory provisions in House Bill (HB) 3074, enacted by the 80th Texas Legislature, Regular Session (2007). HB 3074 repeals Texas Government Code §2308.264(e)(4), which required the Commission to establish rules to ensure that entities contracting with Boards may use, display, and advertise the entity's name when providing workforce services for the Board. HB 3074 removes the requirement that contractor advertising must be allowed.

Texas Government Code, Chapter 2308, and this chapter govern Boards. The repeal of Texas Government Code §2308.264(e)(4) allows the Commission and the Boards the flexibility to decide whether contractors can use, display, and advertise their business name when providing one-stop workforce services for the Boards.

PART II. EXPLANATION OF INDIVIDUAL PROVISIONS

SUBCHAPTER B. ONE-STOP SERVICE DELIVERY NETWORK

The Commission proposes the following amendment to Subchapter B:

§801.33. Advertising

Section 801.33 is deleted to reflect HB 3074, which repeals Texas Government Code §2308.264(e)(4). Repealed §2308.264(e)(4) allowed entities that contract with Boards to use, display, and advertise their business name when providing one-stop workforce services. By deleting this section, the Commission provides Boards the opportunity to make a local determination on whether to allow contractor advertising.

PART III. IMPACT STATEMENTS

Randy Townsend, Chief Financial Officer, has determined that for each year of the first five years the rule is in effect, the following statements will apply:

There are no additional estimated costs to the state and local governments expected as a result of enforcing or administering the rule.

There are no estimated reductions in costs to the state and to local governments as a result of enforcing or administering the rule.

There are no estimated losses or increases in revenue to the state or to local governments as a result of enforcing or administering the rule.

There are no foreseeable implications relating to costs or revenue of the state or local governments as a result of enforcing or administering the rule.

There are no anticipated economic costs to persons required to comply with the rule.

There is no anticipated adverse economic impact on small or microbusinesses as a result of enforcing or administering the rule.

Mark Hughes, Director of Labor Market Information, has determined that there is no significant negative impact upon employment conditions in the state as a result of the rule.

Laurence M. Jones, Director, Workforce Development Division, has determined that for each year of the first five years the rule is in effect, the public benefit anticipated as a result of enforcing the proposed rule will be to comply with the provisions of HB 3074.

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

PART IV. COORDINATION ACTIVITIES

Comments on the proposal may be submitted to TWC Policy Comments, Workforce and UI Policy, 101 East 15th Street, Room 440T, Austin, Texas 78778; faxed to (512) 475-3577; or e-mailed to TWCPolicyComments@twc.state.tx.us. The Commission must receive comments postmarked no later than 30 days from the date this proposal is published in the *Texas Register.*

The repeal is proposed under Texas Labor Code §301.0015 and §302.002(d), which provide the Texas Workforce Commission with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of Agency services and activities.

The proposed repeal affects Texas Labor Code, particularly Chapters 301 and 302, as well as Texas Government Code §2308.

§801.33. Advertising.

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 August 28, 2007.

TRD-200703941

Reagan Miller

Deputy Division Director, Workforce Policy and Service Delivery Branch

Texas Workforce Commission

Earliest possible date of adoption: October 14, 2007

For further information, please call: (512) 475-0829

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 22. EXAMINING BOARDS

PART 9. TEXAS MEDICAL BOARD

CHAPTER 172. TEMPORARY AND LIMITED LICENSES

SUBCHAPTER C. LIMITED LICENSES

22 TAC §172.14

The Texas Medical Board withdraws proposed new §172.14 which appeared in the May 4, 2007, issue of the *Texas Register* (32 TexReg 2445).

Filed with the Office of the Secretary of State on August 31, 2007.

TRD-200704038
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Effective date: August 31, 2007
For further information, please call: (512) 305-7016

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CHAPTER 182. USE OF EXPERTS

22 TAC §182.9

The Texas Medical Board withdraws proposed new §182.9 which appeared in the June 29, 2007, issue of the *Texas Register* (32 TexReg 3958).

Filed with the Office of the Secretary of State on August 31, 2007.

TRD-200704039
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Effective date: August 31, 2007
For further information, please call: (512) 305-7016

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CHAPTER 190. DISCIPLINARY GUIDELINES

SUBCHAPTER B. VIOLATION GUIDELINES

22 TAC §190.8

The Texas Medical Board withdraws the proposed amendment to §190.8 which appeared in the July 20, 2007, issue of the *Texas Register* (32 TexReg 4521).

Filed with the Office of the Secretary of State on August 31, 2007.

TRD-200704040
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Effective date: August 31, 2007
For further information, please call: (512) 305-7016

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PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 291. PHARMACIES

SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

22 TAC §291.33

The Texas State Board of Pharmacy withdraws the proposed amendments to §291.33 which appeared in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3473).

Filed with the Office of the Secretary of State on August 29, 2007.

TRD-200703983
Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Effective date: August 29, 2007
For further information, please call: (512) 305-8028

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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 rule (Government Code, §2001.036). If a rule is adopted without change to the text of 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 19. EDUCATION

PART 2. TEXAS EDUCATION AGENCY

CHAPTER 89. ADAPTATIONS FOR SPECIAL POPULATIONS

The Texas Education Agency (TEA) adopts amendments to §§89.1205, 89.1220, 89.1225, 89.1250; new §89.1207; and the repeal of §89.1260, concerning the state plan for educating limited English proficient students. The amendments to §§89.1205, 89.1220, and 89.1250; new §89.1207; and the repeal of §89.1260 are adopted without changes to the proposed text as published in the June 22, 2007, issue of the *Texas Register* (32 TexReg 3825) and will not be republished. The amendment to §89.1225 is adopted with changes to the proposed text as published in the June 22, 2007, issue. The adopted amendment to §89.1205 and adopted new §89.1207 revise the process of applying for a bilingual exception and/or an English as a second language (ESL) waiver. The other adopted amendments add language regarding the transfer of students out of a special language program in accordance with House Bill (HB) 1, 79th Texas Legislature, Third Called Session, 2006; provide clarification on serving students who receive both special language and special education services; and address submission of information for summer school programs. Section 89.1260 is also repealed to remove monitoring requirements no longer authorized in statute.

In accordance with the Texas Education Code (TEC), Chapter 29, Subchapter B, Bilingual Education and Special Language Programs, the commissioner exercised rulemaking authority establishing rules to guide the implementation of bilingual education and special language programs. The commissioner's rules in 19 TAC Chapter 89, Subchapter BB, adopted to be effective September 1, 1996, establish the policy that every student in the state who has a home language other than English and who is identified as limited English proficient shall be provided a full opportunity to participate in a bilingual education or ESL program. These rules outline the requirements of the bilingual and ESL programs including program content and design, home language survey, the language proficiency assessment committee (LPAC), testing and classification, facilities, parental authority and responsibility, staffing and staff development, required summer school programs, monitoring of programs, and evaluation. Rules in 19 TAC Chapter 89, Subchapter BB, were amended to be effective April 2002. During the statutorily-required rule review of rules in 19 TAC Chapter 89 in 2006, staff identified the need to update the rules. The adopted revisions to 19 TAC Chapter 89, Subchapter BB, include the following rule changes.

Section 89.1205, Required Bilingual Education and English as a Second Language Programs, is amended to delete subsections (g) and (h) regarding bilingual education program exceptions and ESL program waivers. This information is moved to adopted new §89.1207, Exceptions and Waivers, and includes criteria upon which approval would be granted and, if denied, provides for an appeal. The adopted new section also allows for a special accreditation investigation when a district is denied an exception or waiver for more than three consecutive years or has excessive numbers of allowable exemptions. No changes were made to this section since published as proposed.

Section 89.1220, Language Proficiency Assessment Committee, is amended by revising subsection (l) to indicate that a student's exit from a bilingual or ESL program will occur in accordance with the TEC, §29.0561, as added by HB 1, Third Called Session, 2006. A technical update is made for clarification in subsection (i)(5) regarding reference to the state English language proficiency assessment in reading. No changes were made to this section since published as proposed.

Section 89.1225, Testing and Classification of Students, is amended to clarify the process by which testing will be determined for students who receive both special education and special language services. Subsection (f) is revised to add language for determining the appropriate assessment and designated performance level by the admission, review, and dismissal (ARD) committee in conjunction with the LPAC in response to a student individual education program. Subsection (h) is revised to establish exit criteria in accordance with HB 1, Third Called Session, 2006. Subsection (k) is added to include language clarifying the process by which students who receive both special education and special language services are exited from a bilingual education or ESL program. Changes were made to this section since published as proposed. Language in subsection (h)(2) was modified to clarify that English language arts assessment instruments are also to be TEA approved. Language in subsection (i) was modified to reflect that a student may not be exited from a bilingual education or an English as a second language program in prekindergarten or kindergarten, rather than prekindergarten through Grade 1, to be consistent with new language adopted in subsection (h)(2) that allows for students in Grades 1 and 2 to be exited.

Section 89.1250, Required Summer School Programs, is amended to address requirements for district submission of information and eligibility for funding in paragraph (4)(A). No changes were made to this section since published as proposed.

Section 89.1260, Monitoring of Programs and Enforcing Law and Commissioner's Rules, is repealed since the state statute (TEC) no longer authorizes monitoring in this manner. No changes were made to this section since published as proposed.

The public comment period began June 22, 2007, and ended July 22, 2007. Following is a summary of public comments received and corresponding agency responses regarding the pro-

posed revisions to 19 TAC Chapter 89, Adaptations for Special Populations, Subchapter BB, Commissioner's Rules Concerning State Plan for Educating Limited English Proficient Students.

Comment. Concerning §89.1225(h), a comment was received from an educator from the Weatherford Independent School District (ISD) indicating the word "and" is missing between paragraphs (1) and (2) of subsection (h). The comment further indicated that language in paragraph (2) is ambiguous and would be more straightforward if maintained as it was prior to the proposed amendment. The comment also pointed out that, as written, the rule indicates that any assessment instrument is acceptable as long as it is administered in English.

Agency Response. The agency disagrees with the first two points and has maintained language as filed as proposed. First, the language in paragraphs (1) and (2) of subsection (h) are part of a series of three with the word "and" correctly placed between paragraphs (2) and (3). Second, the language in paragraph (2) is consistent with language in the Texas Education Code. The agency agrees with the third point. Language in 19 TAC §89.1225(h)(2) was modified to clarify that English language arts assessment instruments are also to be TEA approved.

Comment. Concerning §89.1225(i), a comment was received from the director of Program Compliance, Division of Curriculum Instruction, for the Carrollton-Farmers Branch ISD, that pointed out a contradiction in the language in new §89.1225(h)(2) that allows for students in Grades 1 and 2 to be exited from a bilingual education or an English as a second language program and §89.1225(i) that indicates a student may not be exited from a bilingual education or an English as a second language program in prekindergarten through Grade 1.

Agency Response. The agency agrees. Language in 19 TAC §89.1225(i) was modified to reflect that a student may not be exited from a bilingual education or an English as a second language program in prekindergarten or kindergarten.

Comment. Concerning §89.1225(k), a comment was received from the director of Special Programs for the Fredericksburg ISD expressing concern that it would be very difficult and unnecessary to convene a committee of all ARD committee members and all LPAC members to make decisions regarding a student who receives both special education and special language services. The comment further expressed the belief that it is not in the best interest of the student for the trained parent member of the LPAC to be in attendance unless this member is the parent of the child under consideration.

Agency Response. The agency disagrees with the comment and has maintained language as filed as proposed. The rule indicates that the two committees must work in conjunction with one another to make decisions. The rule does not require all committee members of both committees to convene at the same time. As written, the rule does not prohibit a district from deciding not to include the trained parent member of the LPAC if it is not in the best interest of the child.

SUBCHAPTER BB. COMMISSIONER'S RULES CONCERNING STATE PLAN FOR EDUCATING LIMITED ENGLISH PROFICIENT STUDENTS

19 TAC §§89.1205, 89.1207, 89.1220, 89.1225, 89.1250

The amendments and new section are adopted under the Texas Education Code, §29.056, which authorizes the agency to adopt rules relating to the identification, assessment, and classification of students of limited English proficiency eligible for entry into the program or exit from the program. Texas Education Code, §29.054, addresses exceptions to bilingual education programs. Texas Education Code, §29.0561, addresses evaluation and reenrollment of exited bilingual students. Texas Education Code, §29.060, establishes preschool, summer school, and extended time programs for bilingual and special language programs.

The amendments and new section implement the Texas Education Code, §§29.051, 29.054, 29.056, 29.0561, and 29.060.

§89.1225. Testing and Classification of Students.

(a) For identifying limited English proficient students, districts shall administer to each student who has a language other than English as identified on the home language survey:

(1) in prekindergarten through Grade 1, an oral language proficiency test approved by the Texas Education Agency (TEA); and

(2) in Grades 2-12, a TEA-approved oral language proficiency test and the English reading and English language arts sections from a TEA-approved norm-referenced measure, or another test approved by TEA, unless the norm-referenced measure is not valid in accordance with subsection (f)(2)(C) of this section.

(b) Districts which provide a bilingual education program shall administer an oral language proficiency test in the home language of the students who are eligible for being served in the bilingual education program. If the home language of the students is Spanish, the district shall administer the Spanish version of the TEA-approved oral language proficiency test which was administered in English. If the home language of the students is other than Spanish, the district shall determine the students' level of proficiency using informal oral language assessment measures.

(c) All the oral language proficiency testing shall be administered by professionals or paraprofessionals who are proficient in the language of the test and trained in language proficiency testing.

(d) The grade levels and the scores on each test which shall identify a student as limited English proficient shall be established by TEA. The commissioner of education shall review the approved list of tests, grade levels, and scores annually and update the list.

(e) Students with a language other than English shall be administered the required oral language proficiency test within four weeks of their enrollment. Norm-referenced assessment instruments, however, may be administered within the established norming period.

(f) For entry into a bilingual education or English as a second language program, a student shall be identified as limited English proficient using the following criteria.

(1) At prekindergarten through Grade 1, the score on the English oral language proficiency test is below the level designated for indicating limited English proficiency under subsection (d) of this section.

(2) At Grades 2-12:

(A) the student's score on the English oral language proficiency test is below the level designated for indicating limited English proficiency under subsection (d) of this section;

(B) the student's score on the reading and language arts sections of the TEA-approved norm-referenced measure at his or her grade level is below the 40th percentile; or

(C) the student's ability in English is so limited that the administration, at his or her grade level, of the reading and language arts sections of a TEA-approved norm-referenced assessment instrument or other test approved by TEA is not valid.

(3) In the absence of data required in paragraph (2)(B) of this subsection, evidence that the student is not academically successful as defined in subsection (j) of this section is required.

(4) The admission review and dismissal (ARD) committee in conjunction with the language proficiency assessment committee shall determine an appropriate assessment instrument and designated level of performance for indicating limited English proficiency as required under subsection (d) of this section for students for whom those tests would be inappropriate as part of the individualized education program (IEP). The decision for entry into a bilingual education or English as a second language program shall be determined by the ARD committee in conjunction with the language proficiency assessment committee in accordance with §89.1220(g) of this title (relating to Language Proficiency Assessment Committee).

(g) Within the four weeks of their initial enrollment in the district, students shall be identified as limited English proficient and enrolled into the required bilingual education or English as a second language program. Prekindergarten and kindergarten students preregistered in the spring shall be identified as limited English proficient and enrolled in the required bilingual education or English as a second language program within four weeks of the start of the school year in the fall.

(h) For exit from a bilingual education or English as a second language program, a student may be classified as English proficient at the end of the school year in which a student would be able to participate equally in a regular, all-English, instructional program. This determination shall be based upon all of the following:

(1) TEA-approved tests that measure the extent to which the student has developed oral and written language proficiency and specific language skills in English;

(2) satisfactory performance on the reading assessment instrument under the Texas Education Code, §39.023(a), or a TEA-approved English language arts assessment instrument administered in English, or a score at or above the 40th percentile on both the English reading and the English language arts sections of a TEA-approved norm-referenced assessment instrument for a student who is enrolled in Grade 1 or 2; and

(3) TEA-approved criterion-referenced written tests when available and the results of a subjective teacher evaluation.

(i) A student may not be exited from the bilingual education or English as a second language program in prekindergarten or kindergarten. A district must ensure that limited English proficient students are prepared to meet academic standards required by TEC, §28.0211.

(j) For determining whether a student who has been exited from a bilingual education or English as a second language program is academically successful, the following criteria shall be used at the end of the school year:

(1) the student meets state performance standards in English of the criterion-referenced assessment instrument required in the Texas Education Code, §39.023, for the grade level as applicable; and

(2) the student has passing grades in all subjects and courses taken.

(k) The ARD committee in conjunction with the language proficiency assessment committee shall determine an appropriate assessment instrument and performance standard requirement for exit under subsection (h) of this section for students for whom those tests would be inappropriate as part of the IEP. The decision to exit a student who receives both special education and special language services from the bilingual education or English as a second language program is determined by the ARD committee in conjunction with the language proficiency assessment committee in accordance with applicable provisions of subsection (h) of 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 August 28, 2007.

TRD-200703950
Cristina De La Fuente-Valadez
Director, Policy Coordination
Texas Education Agency
Effective date: September 17, 2007
Proposal publication date: June 22, 2007
For further information, please call: (512) 475-1497

19 TAC §89.1260

The repeal is adopted under the Texas Education Code, §7.028, which establishes a limitation on compliance monitoring.

The repeal implements the Texas Education Code, §7.028.

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 August 28, 2007.

TRD-200703951
Cristina De La Fuente-Valadez
Director, Policy Coordination
Texas Education Agency
Effective date: September 17, 2007
Proposal publication date: June 22, 2007
For further information, please call: (512) 475-1497

TITLE 22. EXAMINING BOARDS

PART 1. TEXAS BOARD OF ARCHITECTURAL EXAMINERS

CHAPTER 1. ARCHITECTS

SUBCHAPTER A. SCOPE; DEFINITIONS

22 TAC §1.12

The Texas Board of Architectural Examiners adopts an amendment to §1.12, concerning the Joint Advisory Committee of the Texas Board of Architectural Examiners and the Texas Board of Professional Engineers. The amendment is adopted with changes to the proposed text as published in the July 20, 2007, issue of the *Texas Register* (32 TexReg 4519).

The amended rule extends the Joint Committee from its scheduled expiration date of September 1, 2007, to September 1, 2011 to make it possible for the Joint Committee to continue working

on issues arising from the overlap of the jurisdiction of the agencies. The change to the amendment as proposed is to replace the phrase "is abolished on September 1, 2011" with "will expire on September 1, 2011 unless extended by rule."

The agency received no comments concerning the proposal to amend this rule.

There will be no change in the cost to persons required to comply with the section. The rule continues the operations of an advisory committee and imposes no required compliance upon anyone.

The amendment is adopted pursuant to §2110.008(a), Texas Government Code, which allows a state agency to amend its rules to allow an advisory committee to continue in existence after its scheduled abolishment date.

The amendment affects §1051.212 and §1001.216, Texas Occupations Code, which provides for the creation and function of the Joint Advisory Committee.

§1.12. Joint Advisory Committee of the Texas Board of Architectural Examiners and the Texas Board of Professional Engineers.

(a) The Chairman shall appoint three members of the Board and one Architect who is not a member of the Board to serve on a joint advisory committee on the practices of engineering, architecture, and landscape architecture. The three members of the Board to be appointed by the Chairman shall include one Architect, one landscape architect, and one other member of the Board.

(b) Members of the joint advisory committee shall serve staggered six-year terms. The terms of one or two of the members appointed by the Chairman must expire each odd-numbered year.

(c) The joint advisory committee shall meet at least twice each year to address issues resulting from the overlap between activities that constitute the practices of engineering and architecture and the practices of engineering and landscape architecture.

(d) The joint advisory committee shall issue advisory opinions to the Board and the Texas Board of Professional Engineers (TBPE) on subjects including:

(1) whether certain activities constitute the practice of engineering, the practice of architecture, and/or the practice of landscape architecture;

(2) specific disciplinary proceedings initiated by the Board or by TBPE; and

(3) the need for persons working on particular projects to be registered by the Board or licensed by TBPE.

(e) The Board shall notify the joint advisory committee of the final action taken by the Board with regard to a matter addressed in an advisory opinion issued to the Board.

(f) The Board shall enter into a memorandum of understanding with TBPE regarding the joint advisory committee.

(g) The mission of the joint advisory committee shall be to assist the Board and TBPE in protecting the public rather than advancing the interests of either agency or the profession(s) it regulates.

(h) The joint advisory committee will expire on September 1, 2011, unless extended by rule.

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 August 31, 2007.

TRD-200704049
Cathy L. Hendricks
Executive Director
Texas Board of Architectural Examiners
Effective date: September 20, 2007
Proposal publication date: July 20, 2007
For further information, please call: (512) 305-8544

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PART 9. TEXAS MEDICAL BOARD

CHAPTER 161. GENERAL PROVISIONS

22 TAC §161.3

The Texas Medical Board (Board) adopts the amendments to §161.3, relating to the organization and structure of the Board, without changes to the proposed text as published in the June 29, 2007, issue of the *Texas Register* (32 TexReg 3955) and will not be republished.

Prior to publishing the proposed amendments, the Board sought stakeholder input through a stakeholder Group, which made comments on the suggested changes to the rules at a meeting held on May 16, 2007. Comments were incorporated into the published proposed rules.

The Board received no public written comments and no one appeared to testify at the public hearing held on August 24, 2007.

The amendments are adopted under the authority of Texas Occupations Code, §153.001, which provides authority for the Texas Medical Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

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 August 31, 2007.

TRD-200704041
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Effective date: September 20, 2007
Proposal publication date: June 29, 2007
For further information, please call: (512) 305-7016

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CHAPTER 176. HEALTH CARE LIABILITY LAWSUITS AND SETTLEMENTS

22 TAC §§176.1, 176.2, 176.4, 176.6, 176.8, 176.9

The Texas Medical Board adopts amendments to §§176.1, 176.2, 176.4, 176.6, 176.8 and 176.9, concerning Health Care Liability Lawsuits and Settlements, without changes to the proposed text as published in the June 29, 2007, issue of the *Texas Register* (32 TexReg 3956) and will not be republished.

The amendments provide statutory references to Chapter 74 of the Texas Civil Practices and Remedies Code and Chapters 82

and 1901 of the Insurance Code, and updates the name of the Texas Medical Board.

Prior to publishing the proposed amendments, the Board sought stakeholder input through a stakeholder Group, which made comments on the suggested changes to the rules at a meeting held on May 16, 2007. Comments were incorporated into the published proposed rules.

The Board received no public written comments and no one appeared to testify at the public hearing held on August 24, 2007.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously adopts the review of Chapter 176.

The amendments are adopted under the authority of the Texas Occupations Code Annotated, §153.001 and §160.052, which provides authority for the Texas Medical Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

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 August 31, 2007.

TRD-200704042
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Effective date: September 20, 2007
Proposal publication date: June 29, 2007
For further information, please call: (512) 305-7016

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CHAPTER 181. CONTACT LENS PRESCRIPTIONS

22 TAC §§181.2, 181.3, 181.6

The Texas Medical Board adopts amendments to §§181.2, 181.3 and 181.6, concerning Contact Lens Prescriptions, without changes to the proposed text as published in the June 29, 2007, issue of the *Texas Register* (32 TexReg 3957) and will not be republished.

The amendments establish that the verification of a contact lens prescription may substitute for an original signature to create a valid contact lens prescription.

Prior to publishing the proposed amendments, the Board sought stakeholder input through a stakeholder Group, which made comments on the suggested changes to the rules at a meeting held on May 16, 2007. Comments were incorporated into the published proposed rules.

The Board received no public written comments and no one appeared to testify at the public hearing held on August 24, 2007.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously adopts the review of Chapter 181.

The amendments are adopted under the authority of the Texas Occupations Code Annotated, §153.001, which provides authority for the Texas Medical Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

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 August 31, 2007.

TRD-200704043
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Effective date: September 20, 2007
Proposal publication date: June 29, 2007
For further information, please call: (512) 305-7016

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CHAPTER 191. DISTRICT REVIEW COMMITTEES

22 TAC §191.4

The Texas Medical Board adopts amendments to §191.4, concerning Activities and Scope of Authority, without changes to the proposed text as published in the June 29, 2007, issue of the *Texas Register* (32 TexReg 3958) and will not be republished.

The amendment deletes the provision that allows District Review Committee (DRC) members to serve as experts for the purpose of evaluating the medical competency of physicians under investigation. The proposed amendment also establishes that DRC members are allowed to participate in mediation and requires DRC members to have the same qualifications as expert panel members; however they do not need to meet the same selection criteria.

Prior to publishing the proposed amendments, the Board sought stakeholder input through a stakeholder Group, which made comments on the suggested changes to the rules at a meeting held on May 16, 2007. Comments were incorporated into the published proposed rules.

The Board received no public written comments and no one appeared to testify at the public hearing held on August 24, 2007.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously adopts the review of Chapter 191.

The amendment is adopted under the authority of the Texas Occupations Code Annotated, §153.001 and §163.0045, which provides authority for the Texas Medical Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

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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Donald W. Patrick, MD, JD
Executive Director
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For further information, please call: (512) 305-7016

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CHAPTER 194. NON-CERTIFIED RADIOLOGIC TECHNICIANS

22 TAC §§194.2 - 194.6

The Texas Medical Board adopts amendments to §§194.2 - 194.6, concerning Non-Certified Radiologic Technicians, without changes to the proposed text as published in the June 29, 2007, issue of the *Texas Register* (32 TexReg 3959) and will not be republished.

The amendments provide updates regarding the names of the Texas Medical Board and Department of State Health Services, and clarify that NCT registrations that are not renewed within 90 days will be considered expired.

Prior to publishing the proposed amendments, the Board sought stakeholder input through a stakeholder Group, which made comments on the suggested changes to the rules at a meeting held on May 16, 2007. Comments were incorporated into the published proposed rules.

The Board received no public written comments and no one appeared to testify at the public hearing held on August 24, 2007.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously adopts the review of Chapter 194.

The amendments are adopted under the authority of the Texas Occupations Code Annotated, §153.001, which provides authority for the Texas Medical Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

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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CHAPTER 197. EMERGENCY MEDICAL SERVICE

22 TAC §§197.1 - 197.4

The Texas Medical Board adopts amendments to §§197.1 - 197.4, concerning Emergency Medical Service. Sections 197.1, 197.2 and 197.4 are adopted without changes to the proposed text as published in the June 29, 2007, issue of the *Texas Register* (32 TexReg 3960) and will not be republished. Section 197.3 is adopted with changes to the proposed text as published in the June 29, 2007, issue of the *Texas Register* (32 TexReg 3960). The text of the rule will be republished.

The amendments provide updates regarding the names of the Texas Medical Board and Department of State Health Services, require that EMS medical directors report to the board the names and license numbers of all emergency medical personnel who work under a medical director's supervision, and remove the requirement that on-line physicians be familiar with the capabilities of the prehospital providers, as well as local EMS operational policies and regional critical care referral protocols.

The amendment to §197.3 is adopted with changes. The proposed amendment to (b)(15) isn't adopted because after further review, staff determined that including the reporting requirement would be too burdensome to licensees and for staff who would need to process the reports.

Prior to publishing the proposed amendments, the Board sought stakeholder input through a stakeholder Group, which made comments on the suggested changes to the rules at a meeting held on May 16, 2007. Comments were incorporated into the published proposed rules.

The Board received no public written comments and no one appeared to testify at the public hearing held on August 24, 2007.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously adopts the review of Chapter 197.

The amendments are adopted under the authority of the Texas Occupations Code Annotated, §153.001 and §157.003, which provides authority for the Texas Medical Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

§197.3. Off-line Medical Director.

(a) An off-line medical director shall be:

(1) a physician licensed to practice in Texas and shall be registered as an EMS medical director with the Texas Department of State Health Services;

(2) familiar with the design and operation of EMS systems;

(3) experienced in prehospital emergency care and emergency management of ill and injured patients;

(4) actively involved in:

(A) the training and/or continuing education of EMS personnel, under his or her direct supervision, at their respective levels of certification;

(B) the medical audit, review, and critique of the performance of EMS personnel under his or her direct supervision;

(C) the administrative and legislative environments affecting regional and/or state prehospital EMS organizations;

(5) knowledgeable about local multi-casualty plans;

(6) familiar with dispatch and communications operations of prehospital emergency units; and

(7) knowledgeable about laws and regulations affecting local, regional, and state EMS operations.

(b) The off-line medical director shall be required to:

(1) approve the level of prehospital care which may be rendered locally by each of the EMS personnel employed by and/or volunteering with the EMS under the medical director's supervision, regardless of the level of state certification or licensure, before the certificant or licensee is permitted to provide such care to the public;

(2) establish and monitor compliance with field performance guidelines for EMS personnel;

(3) establish and monitor compliance with training guidelines which meet or exceed the minimum standards set forth in the Texas Department of State Health Services EMS certification regulations;

(4) develop, implement, and revise protocols and/or standing delegation orders, if appropriate, governing prehospital care and medical aspects of patient triage, transport, transfer, dispatch, extrication, rescue, and radio-telephone-telemetry communication by the EMS;

(5) direct an effective system audit and quality assurance program;

(6) determine standards and objectives for all medically related aspects of operation of the EMS including the inspection, evaluation, and approval of the system's performance specifications;

(7) function as the primary liaison between the EMS administration and the local medical community, ascertaining and being responsive to the needs of each;

(8) develop a letter or agreement or contract between the medical director(s) and the EMS administration outlining the specific responsibilities and authority of each. The agreement should describe the process or procedure by which a medical director may withdraw responsibility for EMS personnel for noncompliance with the Emergency Medical Services Act, the Health and Safety Code, Chapter 773, the rules adopted in this chapter, and/or accepted medical standards;

(9) take or recommend appropriate remedial or corrective measures for EMS personnel, in conjunction with local EMS administration, which may include, but are not limited to, counseling, retraining, testing, probation, and/or field preceptorship;

(10) suspend a certified EMS individual from medical care duties for due cause pending review and evaluation;

(11) establish the circumstances under which a patient might not be transported;

(12) establish the circumstances under which a patient may be transported against his or her will in accordance with state law, including approval of appropriate procedures, forms, and a review process;

(13) establish criteria for selection of a patient's destination;

(14) develop and implement a comprehensive mechanism for management of patient care incidents, including patient complaints, allegations of substandard care, and deviations from established protocols and patient care standards; and

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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PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 291. PHARMACIES
SUBCHAPTER A. ALL CLASSES OF PHARMACIES

22 TAC §§291.2 - 291.4, 291.7, 291.12, 291.13, 291.15, 291.16, 291.20, 291.21, 291.25 - 291.27

The Texas State Board of Pharmacy adopts the repeal of §291.2, concerning Change of Location and/or Name, §291.3, concerning Change of 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 or 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 repeal is adopted without changes to the proposal as published in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3462).

The repeal provides a more organized Chapter 291, Subchapter A regarding all classes of pharmacies.

No comments were received regarding the proposal.

The repeal is adopted 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 this repeal: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

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 August 29, 2007.

TRD-200703982
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Executive Director/Secretary
Texas State Board of Pharmacy
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Proposal publication date: June 15, 2007
For further information, please call: (512) 305-8028

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22 TAC §§291.2, 291.3, 291.8, 291.10, 291.18, 291.19, 291.22 - 291.24, 291.27

The Texas State Board of Pharmacy adopts new §291.2, concerning Definitions, §291.3, concerning Required Notifications, §291.24, concerning Pharmacy Residency Programs, and §291.27, concerning Confidentiality; amendments to §291.8, concerning Return of Prescription Drugs, §291.10, concerning Pharmacy Balance Registration/Inspection, §291.18, concerning Time Limit for Filing a Compliant, §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 new rules and amendments are adopted without changes to the proposed text as published in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3462).

The amendments and new rules provide a more organized Chapter 291, Subchapter A, regarding all classes of pharmacies.

No comments were received regarding the proposal.

The new rules and amendments are adopted 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 new rules and amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

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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Executive Director/Secretary
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For further information, please call: (512) 305-8028

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22 TAC §291.6

The Texas State Board of Pharmacy adopts amendments to §291.6, concerning Pharmacy License Fees, with changes to the proposed text as published in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3463). The changes to this section are described in this preamble.

Written comments were received from the National Association of Chain Drug Stores (NACDS) with regard to §291.6 which raises pharmacy license fees based on increased expenses. NACDS opposed the 35% fee increased. The Board disagrees with this comment because the Board must be adequately funded to carry out its mission. The Board was however, able to substantially reduce the proposed fee increase for all licensees, including reducing the proposed pharmacy initial and renewal fees from $443, to $385, based on the final appropriations to the agency that were approved by the Texas Legislature.

The amendments are adopted under §§551.002, 554.051, 554.006, and 564.051 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 Board interprets §564.006 as authorizing the agency to adopt rules to establish reasonable and necessary fees to produce sufficient revenue to cover the cost of administering the Act. The Board interprets §564.051 as authorizing the agency to collect a surcharge to fund a program to aid impaired pharmacists and pharmacy students.

The statutes affected by the amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.6. Pharmacy License Fees.

(a) Initial License Fee.

(1) The fee for an initial license shall be $385 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 surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act §564.051;

(B) $10 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(C) $5 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, Occupations Code.

(3) New pharmacy licenses shall be assigned an expiration date and initial registration fee shall be prorated based on the assigned expiration date.

(b) Biennial License Renewal. The Texas State Board of Pharmacy shall require biennial renewal of all pharmacy licenses provided under the Act §561.002.

(c) Renewal Fee.

(1) The fee for biennial renewal of a pharmacy license shall be $385 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 surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act §564.051;

(B) $10 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(C) $2 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, Occupations Code.

(d) Duplicate or Amended Certificates. The fee for issuance of an amended pharmacy license renewal certificate shall be $20.

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. COMMUNITY PHARMACY (CLASS A)

22 TAC §§291.31, 291.32, 291.34

The Texas State Board of Pharmacy adopts amendments to §291.31, concerning Definitions; §291.32, concerning Personnel; and §291.34, concerning Records. The amendments are adopted with changes to the proposed text as published in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3468). The changes to the sections are described in this preamble.

The amendments to §291.31 clarify the definition for hot water, update and clarify the definitions for pharmacy technicians and pharmacy technician trainees, and clarify the definition of prescription drug. The amendments to §291.32 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 amendments to §291.34 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 following comments were received regarding the amendments.

The Texas Society of Health-System Pharmacists commented that the definition of hot water in §291.31 should be consistent with the requirements used for hospital construction standards by the Texas Department of State Health Services (DSHS). DSHS requires hot water to be between 105 and 120 degrees Fahrenheit. The Board agrees with this comment and amended the proposed language to reflect that hot water be a minimum of 105 degrees Fahrenheit.

The National Association of Chain Drug Stores (NACDS) commented that §291.32, which requires a prescription entered into a pharmacy's data processing system be verified by a pharmacist at the time of data entry, would be burdensome and disruptive to pharmacy workflow. The Board disagrees with this comment and believes that prescriptions placed must be checked at the time of data entry in order to ensure that patients receive accurately dispensed prescriptions.

NACDS commented that the amendments to §291.34, requiring pharmacies to provide the Board or its representatives with records in electronic format, would increase costs to pharmacies and would expend hours trying to adapt the pharmacies computer system to meet the Board's needed format. Medco Health Solutions commented that §291.34 recommended that the scope of the amendment be narrowed to only those records relating to prescription records. The Board amended the proposed language to reflect that the records must be provided in a mutually agreeable format.

The amendments are adopted 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: Texas Pharmacy Act, 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) Accurately as prescribed--Dispensing, delivering, and/or distributing a prescription drug order:

(A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed;

(B) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; and

(C) with correct labeling (including directions for use) as ordered by the practitioner. Provided, however, that nothing herein shall prohibit pharmacist substitution if substitution is conducted in strict accordance with applicable laws and rules, including Chapters 562 and 563 of the Texas Pharmacy Act.

(2) Act--The Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Occupations Code, as amended.

(3) Advanced practice nurse--A registered nurse approved by the Texas State Board of Nurse Examiners to practice as an advanced practice nurse on the basis of completion of an advanced education program. The term includes a nurse practitioner, a nurse midwife, a nurse anesthetist, and a clinical nurse specialist.

(4) Automated compounding or counting device--An automated device that compounds, measures, counts, and/or packages a specified quantity of dosage units of a designated drug product.

(5) Automated pharmacy dispensing systems--a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, dispensing, and distribution of medications, and which collects, controls, and maintains all transaction information. "Automated pharmacy dispensing systems" does not mean "Automated compounding or counting devices" or "Automated medication supply devices."

(6) Board--The Texas State Board of Pharmacy.

(7) Carrying out or signing a prescription drug order--The completion of a prescription drug order presigned by the delegating physician, or the signing of a prescription by an advanced practice nurse or physician assistant after the person has been designated with the Texas Medical Board by the delegating physician as a person delegated to sign a prescription. The following information shall be provided on each prescription:

(A) patient's name and address;

(B) name, strength, and quantity of the drug to be dispensed;

(C) directions for use;

(D) the intended use of the drug, if appropriate;

(E) the name, address, and telephone number of the physician;

(F) the name, address, telephone number, identification number, and if the prescription is for a controlled substance, the DEA number of the advanced practice nurse or physician assistant completing the prescription drug order;

(G) the date; and

(H) the number of refills permitted.

(8) Confidential record--Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication order.

(9) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1-4 of the Texas Controlled Substances Act, as amended, or a drug, immediate precursor, or other substance included in Schedules I, II, III, IV, or V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(10) Dangerous drug--A drug or device that:

(A) is not included in Penalty Group 1, 2, 3, or 4, Chapter 481, Health and Safety Code, and is unsafe for self-medication; or

(B) bears or is required to bear the legend:

(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."

(11) Data communication device--An electronic device that receives electronic information from one source and transmits or routes it to another (e.g., bridge, router, switch or gateway).

(12) Deliver or delivery--The actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.

(13) Designated agent--

(A) a licensed nurse, physician assistant, pharmacist, or other individual designated by a practitioner to communicate prescription drug orders to a pharmacist;

(B) a licensed nurse, physician assistant, or pharmacist employed in a health care facility to whom the practitioner communicates a prescription drug order;

(C) an advanced practice nurse or physician assistant authorized by a practitioner to carry out or sign a prescription drug order for dangerous drugs under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code); or

(D) a person who is a licensed vocational nurse or has an education equivalent to or greater than that required for a licensed vocational nurse designated by the practitioner to communicate prescriptions for an advanced practice nurse or physician assistant authorized by the practitioner to sign prescription drug orders under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code).

(14) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(15) Dispensing pharmacist--The pharmacist responsible for the final check of the dispensed prescription before delivery to the patient.

(16) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(17) Downtime--Period of time during which a data processing system is not operable.

(18) Drug regimen review--An evaluation of prescription drug orders and patient medication records for:

(A) known allergies;

(B) rational therapy-contraindications;

(C) reasonable dose and route of administration;

(D) reasonable directions for use;

(E) duplication of therapy;

(F) drug-drug interactions;

(G) drug-food interactions;

(H) drug-disease interactions;

(I) adverse drug reactions; and

(J) proper utilization, including overutilization or underutilization.

(19) Electronic prescription drug order--A prescription drug order which is transmitted by an electronic device to the receiver (pharmacy).

(20) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or, if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(22) Hard copy--A physical document that is readable without the use of a special device (i.e., cathode ray tube (CRT), microfiche reader, etc.).

(23) Hot water-The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).

(24) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

(25) 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) 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) 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) Part-time pharmacist--A pharmacist who works less than full-time.

(29) 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) 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) 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) 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.

(33) 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.

(34) Physician assistant--A physician assistant recognized by the Texas Medical Board as having the specialized education and training required under Subtitle B, Chapter 157, Occupations Code, and issued an identification number by the Texas Medical Board.

(35) 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) 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) 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) 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) State--One of the 50 United States of America, a U.S. territory, or the District of Columbia.

(41) Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.

(42) Written protocol--A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas Medical Board 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) 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) Owner. The owner of a Class A 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 A 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.

(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.

(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. All pharmacists 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).

(B) Sterile Preparations. All pharmacists engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(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.

(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.

(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:

(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;

(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.

(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 bears the person's name and identifies him or her as a 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.

(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) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern.

(4) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist.

§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 a mutually agreeable 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) Records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy.

(3) Records of controlled substances, other than prescription drug orders, 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.

(4) 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:

(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.

(b) Prescriptions.

(1) Professional responsibility.

(A) Pharmacists shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order they dispense. If the pharmacist questions the accuracy or authenticity of a prescription drug order, he/she shall verify the order with the practitioner prior to dispensing.

(B) Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. A pharmacist may not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid patient-practitioner relationship.

(C) Subparagraph (B) of this paragraph does not prohibit a pharmacist from dispensing a prescription when a valid patient-practitioner relationship is not present in an emergency situation (e.g. a practitioner taking calls for the patient's regular practitioner).

(2) Written prescription drug orders.

(A) Practitioner's signature.

(i) Except as noted in clause (ii) of this subparagraph, written prescription drug orders shall be:

(I) manually signed by the practitioner; or

(II) electronically signed by the practitioner using a system which electronically replicates the practitioner's manual signature on the written prescription, provided:

(-a-) that security features of the system require the practitioner to authorize each use; and

(-b-) the prescription is printed on paper that is designed to prevent unauthorized copying of a completed prescription and to prevent the erasure or modification of information written on the prescription by the prescribing practitioner. (For example, the paper contains security provisions against copying that results in some indication on the copy that it is a copy and therefore render the prescription null and void.)

(ii) Prescription drug orders for Schedule II controlled substances shall be issued on an official prescription form as required by the Texas Controlled Substances Act, §481.075, and be manually signed by the practitioner.

(iii) A practitioner may sign a prescription drug order in the same manner as he would sign a check or legal document, e.g. J.H. Smith or John H. Smith.

(iv) Rubber stamped or otherwise reproduced signatures may not be used except as authorized in clause (i) of this subparagraph.

(v) The prescription drug order may not be signed by a practitioner's agent but may be prepared by an agent for the signature of a practitioner. However, the prescribing practitioner is responsible in case the prescription drug order does not conform in all essential respects to the law and regulations.

(B) Prescription drug orders written by practitioners in another state.

(i) Dangerous drug prescription orders. A pharmacist may dispense a prescription drug order for dangerous drugs issued by practitioners in a state other than Texas in the same manner as prescription drug orders for dangerous drugs issued by practitioners in Texas are dispensed.

(ii) Controlled substance prescription drug orders.

(I) A pharmacist may dispense prescription drug order for controlled substances in Schedule II issued by a practitioner in another state provided:

(-a-) the prescription is filled in compliance with a written plan approved by the Director of the Texas Department of Public Safety in consultation with the Board, which provides the manner in which the dispensing pharmacy may fill a prescription for a Schedule II controlled substance;

(-b-) the prescription drug order is an original written prescription issued by 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 (DEA) registration number, and who may legally prescribe Schedule II controlled substances in such other state; and

(-c-) the prescription drug order is not dispensed after the end of the seventh day after the date on which the prescription is issued.

(II) A pharmacist may dispense prescription drug orders for controlled substances in Schedule III, IV, or V issued by a practitioner in another state provided:

(-a-) the prescription drug order is an original written prescription issued by 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 (DEA) registration number, and who may legally prescribe Schedule III, IV, or V controlled substances in such other state;

(-b-) the prescription drug order is not dispensed or refilled more than six months from the initial date of issuance and may not be refilled more than five times; and

(-c-) if there are no refill instructions on the original written prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original written prescription drug order have been dispensed, a new written prescription drug order is obtained from the prescribing practitioner prior to dispensing any additional quantities of controlled substances.

(C) Prescription drug orders written by practitioners in the United Mexican States or the Dominion of Canada.

(i) Controlled substance prescription drug orders. A pharmacist may not dispense a prescription drug order for a Schedule II, III, IV, or V controlled substance issued by a practitioner in the Dominion of Canada or the United Mexican States.

(ii) Dangerous drug prescription drug orders. A pharmacist may dispense a dangerous drug prescription issued by a person licensed in the Dominion of Canada or the United Mexican States as a physician, dentist, veterinarian, or podiatrist provided:

(I) the prescription drug order is an original written prescription; and

(II) if there are no refill instructions on the original written prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original written prescription drug order have been dispensed, a new written prescription drug order shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of dangerous drugs.

(D) Prescription drug orders carried out or signed by an advanced practice nurse or physician assistant.

(i) A pharmacist may dispense a prescription drug order which is carried out or signed by an advanced practice nurse or physician assistant provided the advanced practice nurse or physician assistant is practicing in accordance with Subtitle B, Chapter 157, Occupations Code.

(ii) Each practitioner shall designate in writing the name of each advanced practice nurse or physician assistant authorized to carry out or sign a prescription drug order pursuant to Subtitle B, Chapter 157, Occupations Code. A list of the advanced practice nurses or physician assistants designated by the practitioner must be maintained in the practitioner's usual place of business. On request by a pharmacist, a practitioner shall furnish the pharmacist with a copy of the written authorization for a specific advanced practice nurse or physician assistant.

(E) Prescription drug orders for Schedule II controlled substances. No Schedule II controlled substance may be dispensed without a written prescription drug order of a practitioner on an official prescription form as required by the Texas Controlled Substances Act, §481.075.

(3) Verbal prescription drug orders.

(A) A verbal prescription drug order from a practitioner or a practitioner's designated agent may only be received by a pharmacist or a pharmacist-intern under the direct supervision of a pharmacist.

(B) A practitioner shall designate in writing the name of each agent authorized by the practitioner to communicate prescriptions verbally for the practitioner. The practitioner shall maintain at the practitioner's usual place of business a list of the designated agents. The practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a specific agent on the pharmacist's request.

(C) A pharmacist may not dispense a verbal prescription drug order for a Schedule III, IV, or V controlled substance issued by a practitioner licensed in another state unless the practitioner is also registered under the Texas Controlled Substances Act.

(D) A pharmacist may not dispense a verbal prescription drug order for a dangerous drug or a controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(4) Electronic prescription drug orders. For the purpose of this subsection, prescription drug orders shall be considered the same as verbal prescription drug orders.

(A) An electronic prescription drug order may be transmitted by a practitioner or a practitioner's designated agent:

(i) directly to a pharmacy; or

(ii) through the use of a data communication device provided:

(I) the confidential prescription information is not altered during transmission; and

(II) confidential patient information is not accessed or maintained by the operator of the data communication device other than for legal purposes under federal and state law.

(B) A practitioner shall designate in writing the name of each agent authorized by the practitioner to electronically transmit prescriptions for the practitioner. The practitioner shall maintain at the practitioner's usual place of business a list of the designated agents. The practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a specific agent on the pharmacist's request.

(C) A pharmacist may not dispense an electronic prescription drug order for a:

(i) Schedule II controlled substance, except as authorized for faxed prescriptions in §481.074, Health and Safety Code;

(ii) Schedule III, IV, or V controlled substance issued by a practitioner licensed in another state unless the practitioner is also registered under the Texas Controlled Substances Act; or

(iii) dangerous drug or controlled substance issued by a practitioner licensed in the Dominion of Canada or the United Mexican States unless the practitioner is also licensed in Texas.

(5) Original prescription drug order records.

(A) Original prescriptions shall be maintained by the pharmacy in numerical order and remain legible for a period of two years from the date of filling or the date of the last refill dispensed.

(B) If an original prescription drug order is changed, such prescription order shall be invalid and of no further force and effect; if additional drugs are to be dispensed, a new prescription drug order with a new and separate number is required.

(C) Original prescriptions shall be maintained in three separate files as follows:

(i) prescriptions for controlled substances listed in Schedule II;

(ii) prescriptions for controlled substances listed in Schedules III - V; and

(iii) prescriptions for dangerous drugs and nonprescription drugs.

(D) Original prescription records other than prescriptions for Schedule II controlled substances may be stored on microfilm, microfiche, or other system which is capable of producing a direct image of the original prescription record, e.g., digitalized imaging system. If original prescription records are stored in a direct imaging system, the following is applicable:

(i) the record of refills recorded on the original prescription must also be stored in this system;

(ii) the original prescription records must be maintained in numerical order and separated in three files as specified in subparagraph (C) of this paragraph; and

(iii) the pharmacy must provide immediate access to equipment necessary to render the records easily readable.

(6) Prescription drug order information.

(A) All original prescriptions shall bear:

(i) name of the patient, or if such drug is for an animal, the species of such animal and the name of the owner;

(ii) address of the patient, provided, however, a prescription for a dangerous drug is not required to bear the address of the patient if such address is readily retrievable on another appropriate, uniformly maintained pharmacy record, such as medication records;

(iii) name, and if for a controlled substance, the address and DEA registration number of the practitioner;

(iv) name and strength of the drug prescribed;

(v) quantity prescribed;

(vi) directions for use;

(vii) intended use for the drug unless the practitioner determines the furnishing of this information is not in the best interest of the patient; and

(viii) date of issuance.

(B) All original electronic prescription drug orders shall bear:

(i) name of the patient, if such drug is for an animal, the species of such animal, and the name of the owner;

(ii) address of the patient, provided, however, a prescription for a dangerous drug is not required to bear the address of the patient if such address is readily retrievable on another appropriate, uniformly maintained pharmacy record, such as medication records;

(iii) name, and if for a controlled substance, the address and DEA registration number of the practitioner;

(iv) name and strength of the drug prescribed;

(v) quantity prescribed;

(vi) directions for use;

(vii) indications for use, unless the practitioner determines the furnishing of this information is not in the best interest of the patient;

(viii) date of issuance;

(ix) a statement which indicates that the prescription has been electronically transmitted (e.g., Faxed to or electronically transmitted to:);

(x) name, address, and electronic access number of the pharmacy to which the prescription was transmitted;

(xi) telephone number of the prescribing practitioner;

(xii) date the prescription drug order was electronically transmitted to the pharmacy, if different from the date of issuance of the prescription; and

(xiii) if transmitted by a designated agent, the full name of the designated agent.

(C) All original written prescriptions carried out or signed by an advanced practice nurse or physician assistant in accordance with Subtitle B, Chapter 157, Occupations Code, shall bear:

(i) name and address of the patient;

(ii) name, address, telephone number, and if the prescription is for a controlled substance, the DEA number of the supervising practitioner;

(iii) name, identification number, original signature and if the prescription is for a controlled substance, the DEA number of the advanced practice nurse or physician assistant;

(iv) address and telephone number of the clinic at which the prescription drug order was carried out or signed;

(v) name, strength, and quantity of the drug;

(vi) directions for use;

(vii) indications for use, if appropriate;

(viii) date of issuance; and

(ix) number of refills authorized.

(D) At the time of dispensing, a pharmacist is responsible for documenting the following information on either the original hard-copy prescription or in the pharmacy's data processing system:

(i) unique identification number of the prescription drug order;

(ii) initials or identification code of the dispensing pharmacist;

(iii) effective January 1, 2009, initials or identification code of the pharmacy technician or pharmacy technician trainee performing data entry of the prescription, if applicable;

(iv) quantity dispensed, if different from the quantity prescribed;

(v) date of dispensing, if different from the date of issuance; and

(vi) brand name or manufacturer of the drug product actually dispensed, if the drug was prescribed by generic name or if a drug product other than the one prescribed was dispensed pursuant to the provisions of the Act, Chapters 562 and 563.

(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) 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) Patient medication records.

(1) A patient medication record system shall be maintained by the pharmacy for patients to whom prescription drug orders are dispensed.

(2) The patient medication record system shall provide for the immediate retrieval of information for the previous 12 months which is necessary for the dispensing pharmacist to conduct a prospective drug regimen review at the time a prescription drug order is presented for dispensing.

(3) The pharmacist-in-charge shall assure that a reasonable effort is made to obtain and record in the patient medication record at least the following information:

(A) full name of the patient for whom the drug is prescribed;

(B) address and telephone number of the patient;

(C) patient's age or date of birth;

(D) patient's gender;

(E) any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs currently being used by the patient which may relate to prospective drug regimen review;

(F) pharmacist's comments relevant to the individual's drug therapy, including any other information unique to the specific patient or drug; and

(G) a list of all prescription drug orders dispensed (new and refill) to the patient by the pharmacy during the last two years. Such list shall contain the following information:

(i) date dispensed;

(ii) name, strength, and quantity of the drug dispensed;

(iii) prescribing practitioner's name;

(iv) unique identification number of the prescription; and

(v) name or initials of the dispensing pharmacists.

(4) A patient medication record shall be maintained in the pharmacy for two years. If patient medication records are maintained in a data processing system, all of the information specified in this subsection shall be maintained in a retrievable form for two years and information for the previous 12 months shall be maintained on-line. Effective January 1, 2009, a patient medication record must contain documentation of any modification, change, or manipulation to a patient profile.

(5) Nothing in this paragraph shall be construed as requiring a pharmacist to obtain, record, and maintain patient information other than prescription drug order information when a patient or patient's agent refuses to provide the necessary information for such patient medication records.

(d) Prescription drug order records maintained in a manual system.

(1) Original prescriptions shall be maintained in three files as specified in subsection (b)(5)(C) of this section.

(2) Refills.

(A) Each time a prescription drug order is refilled, a record of such refill shall be made:

(i) on the back of the prescription by recording the date of dispensing, the written initials or identification code of the dispensing pharmacist, effective January 1, 2009, the initials or identification code of the pharmacy technician or pharmacy technician trainee preparing the prescription label, if applicable, and the amount dispensed. (If the pharmacist merely initials and dates the back of the prescription drug order, he or she shall be deemed to have dispensed a refill for the full face amount of the prescription drug order); or

(ii) on another appropriate, uniformly maintained, readily retrievable record, such as medication records, which indicates by patient name the following information:

(I) unique identification number of the prescription;

(II) name and strength of the drug dispensed;

(III) date of each dispensing;

(IV) quantity dispensed at each dispensing;

(V) initials or identification code of the dispensing pharmacist;

(VI) effective January 1, 2009, initials or identification code of the pharmacy technician or pharmacy technician trainee preparing the prescription label, if applicable; and

(VII) total number of refills for the prescription.

(B) If refill records are maintained in accordance with subparagraph (A)(ii) of this paragraph, refill records for controlled substances in Schedules III - V shall be maintained separately from refill records of dangerous drugs and nonprescription drugs.

(3) Authorization of refills. Practitioner authorization for additional refills of a prescription drug order shall be noted on the original prescription, in addition to the documentation of dispensing the refill.

(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;

(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;

(D) both the original and the transferred prescription drug order 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 drug order 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 information is transferred; and

(V) name of the pharmacist or pharmacist intern transferring the prescription drug order information.

(5) A pharmacist or pharmacist intern may not refuse to transfer original prescription information to another pharmacist or pharmacist intern who is acting on behalf of a patient and who is making a request for this information as specified in paragraph (4) of this subsection.

(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 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) General requirements for records maintained in a data processing system.

(A) Compliance with data processing system requirements. If a Class A (community) pharmacy's data processing system is not in compliance with this subsection, the pharmacy must maintain a manual recordkeeping system as specified in subsection (d) of this section.

(B) Original prescriptions. Original prescriptions shall be maintained in three files as specified in subsection (b)(5)(C) of this section.

(C) Requirements for backup systems.

(i) The pharmacy shall maintain a backup copy of information stored in the data processing system using disk, tape, or other electronic backup system and update this backup copy on a regular basis, at least monthly, to assure that data is not lost due to system failure.

(ii) Data processing systems shall have a workable (electronic) data retention system which can produce an audit trail of drug usage for the preceding two years as specified in paragraph (2)(G) of this subsection.

(D) Change or discontinuance of a data processing system.

(i) Records of dispensing. A pharmacy that changes or discontinues use of a data processing system must:

(I) transfer the records of dispensing to the new data processing system; or

(II) purge the records of dispensing to a printout which contains the same information required on the daily printout as specified in paragraph (2)(B) of this subsection. The information on this hard-copy printout shall be sorted and printed by prescription number and list each dispensing for this prescription chronologically.

(ii) Other records. A pharmacy that changes or discontinues use of a data processing system must:

(I) transfer the records to the new data processing system; or

(II) purge the records to a printout which contains all of the information required on the original document.

(iii) Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(E) Loss of data. The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(2) Records of dispensing.

(A) Each time a prescription drug order is filled or refilled, a record of such dispensing shall be entered into the data processing system.

(B) 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 in the data processing system. The documentation of any modification, change, or manipulation to a record of dispensing shall include the identification of the individual responsible for the alteration. Should the data processing system not be able to record a modification, change, or manipulation to a record of dispensing, the information should be clearly documented on the hard-copy prescription.

(C) The data processing system shall have the capacity to produce a daily hard-copy printout of all original prescriptions dispensed and refilled. This hard-copy printout shall contain the following information:

(i) unique identification number of the prescription;

(ii) date of dispensing;

(iii) patient name;

(iv) prescribing practitioner's name;

(v) name and strength of the drug product actually dispensed; if generic name, the brand name or manufacturer of drug dispensed;

(vi) quantity dispensed;

(vii) initials or an identification code of the dispensing pharmacist;

(viii) effective January 1, 2009, initials or an identification code of the pharmacy technician or pharmacy technician trainee performing data entry of the prescription, if applicable;

(ix) if not immediately retrievable via CRT display, the following shall also be included on the hard-copy printout:

(I) patient's address;

(II) prescribing practitioner's address;

(III) practitioner's DEA registration number, if the prescription drug order is for a controlled substance;

(IV) quantity prescribed, if different from the quantity dispensed;

(V) date of issuance of the prescription drug order, if different from the date of dispensing; and

(VI) total number of refills dispensed to date for that prescription drug order; and

(x) effective January 1, 2009, any changes made to a record of dispensing.

(D) The daily hard-copy printout shall be produced within 72 hours of the date on which the prescription drug orders were dispensed and shall be maintained in a separate file at the pharmacy. Records of controlled substances shall be readily retrievable from records of noncontrolled substances.

(E) Each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard-copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document (e.g., J.H. Smith, or John H. Smith) within seven days from the date of dispensing.

(F) In lieu of the printout described in subparagraph (C) of this paragraph, the pharmacy shall maintain a log book in which each individual pharmacist using the data processing system shall sign a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is correct as entered. Such log book shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing; provided, however, that the data processing system can produce the hard-copy printout on demand by an authorized agent of the Texas State Board of Pharmacy. If no printer is available on site, the hard-copy printout shall be available within 72 hours with a certification by the individual providing the printout, which states that the printout is true and correct as of the date of entry and such information has not been altered, amended, or modified.

(G) The pharmacist-in-charge is responsible for the proper maintenance of such records and responsible that such data processing system can produce the records outlined in this section and that such system is in compliance with this subsection.

(H) The data processing system shall be capable of producing a hard-copy printout of an audit trail for all dispensings (original and refill) of any specified strength and dosage form of a drug (by either brand or generic name or both) during a specified time period.

(i) Such audit trail shall contain all of the information required on the daily printout as set out in subparagraph (C) of this paragraph.

(ii) The audit trail required in this subparagraph shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy.

(I) 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.

(J) The data processing system shall provide on-line retrieval (via CRT display or hard-copy printout) of the information set out in subparagraph (C) of this paragraph of:

(i) the original controlled substance prescription drug orders currently authorized for refilling; and

(ii) the current refill history for Schedules III, IV, and V controlled substances for the immediately preceding six-month period.

(K) In the event that a pharmacy which uses a data processing system experiences system downtime, the following is applicable:

(i) an auxiliary procedure shall ensure that refills are authorized by the original prescription drug order and that the maximum number of refills has not been exceeded or authorization from the prescribing practitioner shall be obtained prior to dispensing a refill; and

(ii) all of the appropriate data shall be retained for on-line data entry as soon as the system is available for use again.

(3) Authorization of refills. Practitioner authorization for additional refills of a prescription drug order shall be noted as follows:

(A) on the hard-copy prescription drug order;

(B) on the daily hard-copy printout; or

(C) via the CRT display.

(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) A pharmacist or pharmacist intern may not refuse to transfer original prescription information to another pharmacist or pharmacist intern who is acting on behalf of a patient and who is making a request for this information as specified in paragraphs (4) and (5) of this subsection.

(f) Limitation to one type of recordkeeping system. When filing prescription drug order information a pharmacy may use only one of the two systems described in subsection (d) or (e) of this section.

(g) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practitioner, another pharmacy, or other registrant, without being registered to distribute, under the following conditions.

(1) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to dispense that controlled substance.

(2) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed and distributed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled substances.

(3) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained which indicates:

(A) the actual date of distribution;

(B) the name, strength, and quantity of controlled substances distributed;

(C) the name, address, and DEA registration number of the distributing pharmacy; and

(D) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

(4) If the distribution is for a Schedule I or II controlled substance, the following is applicable.

(A) The pharmacy, practitioner, or other registrant who is receiving the controlled substances shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222C) to the distributing pharmacy.

(B) The distributing pharmacy shall:

(i) complete the area on the DEA order form (DEA 222C) titled "To Be Filled in by Supplier";

(ii) maintain Copy 1 of the DEA order form (DEA 222C) at the pharmacy for two years; and

(iii) forward Copy 2 of the DEA order form (DEA 222C) to the Divisional Office of the Drug Enforcement Administration.

(h) Other records. Other records to be maintained by a pharmacy:

(1) a permanent log of the initials or identification codes which will identify each dispensing pharmacist by name (the initials or identification code shall be unique to ensure that each pharmacist can be identified, i.e., identical initials or identification codes shall not be used);

(2) Copy 3 of DEA order form (DEA 222C) which has been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents;

(3) a hard copy of the power of attorney to sign DEA 222C order forms (if applicable);

(4) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify that the controlled drugs listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances;

(5) suppliers' credit memos for controlled substances and dangerous drugs;

(6) a hard copy of inventories required by §291.17 of this title (relating to Inventory Requirements);

(7) hard-copy reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;

(8) a hard copy of the Schedule V nonprescription register book;

(9) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(10) a hard copy of any notification required by the Texas Pharmacy Act or the sections in this chapter, including, but not limited to, the following:

(A) reports of theft or significant loss of controlled substances to DEA, Department of Public Safety, and the board;

(B) notifications of a change in pharmacist-in-charge of a pharmacy; and

(C) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and disease.

(i) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for invoices and financial data shall comply with the following procedures.

(1) Controlled substance records. Invoices and financial data for controlled substances may be maintained at a central location provided the following conditions are met.

(A) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of the Drug Enforcement Administration as required by Title 21, Code of Federal Regulations, §1304.04(a), and submits a copy of this written notification to the Texas State Board of Pharmacy. Unless the registrant is informed by the divisional director of the Drug Enforcement Administration that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director.

(B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this paragraph.

(C) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the pharmacy.

(2) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location.

(3) Access to records. If the records are kept on microfilm, computer media, or in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records.

(4) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy location within two business days of written request of a board agent or any other authorized official.

(j) Ownership of pharmacy records. For the purposes of these sections, a pharmacy licensed under the Act is the only entity which may legally own and maintain prescription drug records.

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 August 29, 2007.

TRD-200703984
Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Effective date: September 18, 2007
Proposal publication date: June 15, 2007
For further information, please call: (512) 305-8028

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22 TAC §291.37, §291.38

The Texas State Board of Pharmacy adopts the repeal of §291.37, concerning Centralized Prescription Dispensing and §291.38, concerning Central Prescription Drug or Medication Order Processing. The repeal is adopted without changes to the proposal as published in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3480).

The repeal of §291.37 and §291.38 are adopted as new rules in new Subchapter G of Chapter 291 and are published elsewhere in this issue of the *Texas Register*.

No comments were received regarding the proposal.

The repeal is adopted 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: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

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 August 29, 2007.

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SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)

22 TAC §§291.72 - 291.76

The Texas State Board of Pharmacy adopts amendments to §291.72, concerning Definitions; §291.73, concerning Personnel; §291.74, concerning Operational Standards; §291.75, concerning Records; and §291.76, concerning Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center. The amendments to §291.73 and §291.74 are adopted without changes to the proposed text as published in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3481). The amendments to §291.72, 291.75, and 291.76 are adopted with changes to the proposed text. The changes are described in this preamble.

The amendments to §291.72 clarify the definition for hot water and update and clarify the definitions for pharmacy technicians and pharmacy technician trainees. The amendments to §291.73 update the rules to include pharmacy technician trainees and clarify the responsibilities of owners of Class C pharmacies. The amendments to §291.74 allow Class C pharmacies to distribute repackaged drugs to other Class C pharmacies under common ownership in accordance with Senate Bill 492 passed by the 79th Texas Legislature, Regular Session. The amendments to §291.75 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 amendments to §291.76 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.

The following comments were received regarding adoption of the amendments.

The Texas Society of Health-System Pharmacists (TSHP) commented that the definition of hot water in §291.72 should be consistent with the requirements used for hospital construction standards by the Texas Department of State Health Services (DSHS). DSHS requires hot water to be between 105 and 120 degrees Fahrenheit. The Board agrees with this comment and amended the proposed language.

NACDS commented that the amendments to §291.75 and §291.76, requiring pharmacies to provide the Board or its representatives with records in electronic format, would increase costs to pharmacies and would expend hours trying to adapt the pharmacies computer system to meet the Board's needed format. The Board amended the proposed language to reflect that the records must be provided in a mutually agreeable format.

TSHP provided grammatical corrections to §291.76. The Board agrees with the recommendations and made the necessary corrections.

The amendments are adopted 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: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.72. Definitions.

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Accurately as prescribed--Distributing and/or delivering a medication drug order:

(A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed;

(B) with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; and

(C) with correct labeling as ordered by the practitioner and required by rule.

(2) Act--The Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Occupations Code, as amended.

(3) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

(B) the patient at the direction of a practitioner.

(4) Automated compounding or counting device--An automated device that compounds, measures, counts and/or packages a specified quantity of dosage units of a designated drug product.

(5) Automated medication supply system--a mechanical system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(6) Board--The State Board of Pharmacy.

(7) Confidential record--Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication drug order.

(8) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the facility in areas that pertain to the practice of pharmacy.

(9) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug, immediate precursor, or other substance included in Schedules I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(10) Dangerous drug--A drug or device that:

(A) is not included in Penalty Group 1, 2, 3, or 4, Chapter 481, Health and Safety Code, and is unsafe for self-medication; or

(B) bears or is required to bear the legend:

(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."

(11) 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.

(12) Direct copy--Electronic copy or carbonized copy of a medication order, including a facsimile (FAX), tele-autograph, or a copy transmitted between computers.

(13) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(14) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(15) Distributing pharmacist--The pharmacist who checks the medication order prior to distribution.

(16) Downtime--Period of time during which a data processing system is not operable.

(17) Drug regimen review--

(A) An evaluation of medication orders and patient medication records for:

(i) known allergies;

(ii) rational therapy--contraindications;

(iii) reasonable dose and route of administration;

(iv) reasonable directions for use;

(v) duplication of therapy;

(vi) drug-drug interactions;

(vii) drug-food interactions;

(viii) drug-disease interactions;

(ix) adverse drug reactions; and

(x) proper utilization, including overutilization or underutilization.

(B) The drug regimen review may be conducted prior to administration of the first dose (prospective) or after administration of the first dose (retrospective).

(18) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(19) Expiration date--The date (and time, when applicable) beyond which a product should not be used.

(20) Facility--

(A) a hospital or other in-patient facility that is licensed under Chapter 241 or 577, Health and Safety Code;

(B) a hospice in-patient facility that is licensed under Chapter 142, Health and Safety Code;

(C) an ambulatory surgical center licensed under Chapter 243, Health and Safety Code; or

(D) a hospital maintained or operated by the state.

(21) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other hospital department (excluding the pharmacy) for the purpose of administration to a patient of the facility.

(22) Formulary--List of drugs approved for use in the facility by the committee which performs the pharmacy and therapeutics function for the facility.

(23) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(24) Hard copy--A physical document that is readable without the use of a special device (i.e., cathode ray tube (CRT), microfiche reader, etc).

(25) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).

(26) 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) 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) 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) Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

(30) 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) Part-time pharmacist--A pharmacist either employed or under contract, who routinely works less than full-time.

(32) 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) 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) 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) 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) 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.

(37) 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.

(38) 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) 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) 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) 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) 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) Sample--A prescription drug which is not intended to be sold and is intended to promote the sale of the drug.

(44) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and Safety Code, Chapter 481, as amended.

(45) 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) Unusable drugs--Drugs or devices that are unusable for reasons, such as they are adulterated, misbranded, expired, defective, or recalled.

(47) Written protocol--A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas Medical Board under the Texas Medical Practice Act Subtitle B, Chapter 157, Occupations Code.

§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 a mutually agreeable 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) Records of controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

(3) 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, redlined, or in some other manner readily identifiable apart from all other items appearing on the record.

(4) 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:

(A) the records in the alternative data retention system contain all of the information required on the manual record; and

(B) 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.

(b) Outpatient records.

(1) Outpatient records shall be maintained as provided in §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Records), contained in Community Pharmacy (Class A).

(2) Outpatient prescriptions, including, but not limited to, furlough and discharge prescriptions, that are written by the practitioner must be written on a form which meets the requirements of the Act, §562.006. Medication order forms or copies thereof do not meet the requirements for outpatient forms.

(3) Controlled substances listed in Schedule II must be written on an official prescription form in accordance with the Texas Controlled Substances Act, §481.075, and rules promulgated pursuant to the Texas Controlled Substances Act, unless exempted by the Texas controlled substances regulations, 37 TAC §13.74 (relating to Exceptions to Use of Forms). Outpatient prescriptions for Schedule II

controlled substances that are exempted from the official prescription requirement must be manually signed by the practitioner.

(c) Inpatient records.

(1) Original medication orders.

(A) Each original medication order shall bear the following information:

(i) patient name and room number or identification number;

(ii) drug name, strength, and dosage form;

(iii) directions for use;

(iv) date; and

(v) signature or electronic signature of the practitioner or that of his or her authorized agent.

(B) Original medication order shall be maintained with the medication administration records of the patients.

(2) Patient medication records (PMR). A patient medication record shall be maintained for each inpatient of the facility. The PMR shall contain at a minimum the following information.

(A) Patient information:

(i) patient name and room number or identification number;

(ii) gender, and date of birth or age;

(iii) weight and height;

(iv) known drug sensitivities and allergies to drugs and/or food;

(v) primary diagnoses and chronic conditions;

(vi) primary physician; and

(vii) other drugs the patient is receiving.

(B) Medication order information:

(i) date of distribution;

(ii) drug name, strength, and dosage form; and

(iii) directions for use.

(3) Controlled substances records. Controlled substances records shall be maintained as follows.

(A) All records for controlled substances shall be maintained in a readily retrievable manner.

(B) Controlled substances records shall be maintained in a manner to establish receipt and distribution of all controlled substances.

(4) Schedule II controlled substances records. Records of controlled substances listed in Schedule II shall be maintained as follows.

(A) Records of controlled substances listed in Schedule II shall be maintained separately from records of controlled substances in Schedules III, IV, and V, and all other records.

(B) An institutional pharmacy shall maintain a perpetual inventory of any controlled substance listed in Schedule II.

(C) Distribution records for controlled substances listed in Schedule II shall bear the following information:

(i) patient's name;

(ii) prescribing or attending practitioner;

(iii) name of drug, dosage form, and strength;

(iv) time and date of administration to patient and quantity administered;

(v) signature (first initial and last name or full signature) or electronic signature of the individual administering the controlled substance;

(vi) returns to the pharmacy; and

(vii) waste (waste is required to be witnessed and cosigned, electronically or manually, by another individual).

(5) Floor stock records.

(A) Distribution records for Schedule II - V controlled substances floor stock shall include the following information:

(i) patient's name;

(ii) prescribing or attending practitioner;

(iii) name of controlled substance, dosage form, and strength;

(iv) time and date of administration to patient;

(v) quantity administered;

(vi) signature (first initial and last name or full signature) or electronic signature of the individual administering drug;

(vii) returns to the pharmacy; and

(viii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(B) The record required by subparagraph (A) of this paragraph shall be maintained separately from patient records.

(C) A pharmacist shall review distribution records with medication orders on a periodic basis to verify proper usage of drugs, not to exceed 30 days between such reviews.

(6) General requirements for records maintained in a data processing system.

(A) Noncompliance with data processing requirements. If a hospital pharmacy's data processing system is not in compliance with the Board's requirements, the pharmacy must maintain a manual recordkeeping system.

(B) Requirements for back-up systems. The facility shall maintain a back-up copy of information stored in the data processing system using disk, tape, or other electronic back-up system and update this back-up copy on a regular basis, at least monthly, to assure that data is not lost due to system failure.

(C) Change or discontinuance of a data processing system.

(i) Records of distribution and return for all controlled substances, nalbuphine (e.g., Nubain), tripelennamine (e.g., PBZ) and carisoprodol (e.g., Soma). A pharmacy that changes or discontinues use of a data processing system must:

(I) transfer the records to the new data processing system; or

(II) purge the records to a printout which contains the same information as required on the audit trail printout as specified in paragraph (7)(B) of this subsection. The information on

this printout shall be sorted and printed by drug name and list all distributions/returns chronologically.

(ii) Other records. A pharmacy that changes or discontinues use of a data processing system must:

(I) transfer the records to the new data processing system; or

(II) purge the records to a printout which contains all of the information required on the original document.

(iii) Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(D) Loss of data. The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(7) Data processing system maintenance of records for the distribution and return of all controlled substances, nalbuphine (e.g., Nubain), tripelennamine (e.g., PBZ), and carisoprodol (e.g., Soma) to the pharmacy.

(A) Each time a controlled substance, nalbuphine (e.g., Nubain), tripelennamine (e.g., PBZ), or carisoprodol (e.g., Soma) is distributed from or returned to the pharmacy, a record of such distribution or return shall be entered into the data processing system.

(B) The data processing system shall have the capacity to produce a hard copy printout of an audit trail of drug distribution and return for any strength and dosage form of a drug (by either brand or generic name or both) during a specified time period. This printout shall contain the following information:

(i) patient's name and room number or patient's facility identification number;

(ii) prescribing or attending practitioner's name;

(iii) name, strength, and dosage form of the drug product actually distributed;

(iv) total quantity distributed from and returned to the pharmacy;

(v) if not immediately retrievable via CRT display, the following shall also be included on the printout:

(I) prescribing or attending practitioner's address; and

(II) practitioner's DEA registration number, if the medication order is for a controlled substance.

(C) An audit trail printout for each strength and dosage form of these drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the facility. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

(D) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this paragraph shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law enforcement or regulatory agencies.

(8) Failure to maintain records. Failure to provide 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.

(9) Data processing system downtime. In the event that a hospital pharmacy which uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for on-line data entry as soon as the system is available for use again.

(d) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practitioner, another pharmacy or other registrant, without being registered to distribute, under the following conditions.

(1) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to dispense that controlled substance.

(2) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed or distributed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled substances.

(3) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained which indicates:

(A) the actual date of distribution;

(B) the name, strength, and quantity of controlled substances distributed;

(C) the name, address, and DEA registration number of the distributing pharmacy; and

(D) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

(4) If the distribution is for a Schedule I or II controlled substance, the following is applicable.

(A) The pharmacy, practitioner or other registrant who is receiving the controlled substances shall issue copy 1 and copy 2 of a DEA order form (DEA 222) to the distributing pharmacy.

(B) The distributing pharmacy shall:

(i) complete the area on the DEA order form (DEA 222) titled TO BE FILLED IN BY SUPPLIER;

(ii) maintain copy 1 of the DEA order form (DEA 222) at the pharmacy for two years; and

(iii) forward copy 2 of the DEA order form (DEA 222) to the divisional office of the Drug Enforcement Administration.

(e) Other records. Other records to be maintained by a pharmacy:

(1) a permanent log of the initials or identification codes which will identify pharmacy personnel by name (the initials or identification code shall be unique to ensure that each person can be identified, i.e., identical initials or identification codes cannot be used);

(2) copy 3 of DEA order form (DEA 222) which has been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents;

(3) a hard copy of the power of attorney to sign DEA 222 order forms (if applicable);

(4) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify that the controlled drugs listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances;

(5) suppliers' credit memos for controlled substances and dangerous drugs;

(6) a hard copy of inventories required by §291.17 of this title (relating to Inventory Requirements) except that a perpetual inventory of controlled substances listed in Schedule II may be kept in a data processing system if the data processing system is capable of producing a hard copy of the perpetual inventory on-site;

(7) hard copy reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;

(8) a hard copy Schedule V nonprescription register book;

(9) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(10) a hard copy of any notification required by the Texas Pharmacy Act or these sections including, but not limited to, the following:

(A) reports of theft or significant loss of controlled substances to DEA, DPS, and the board;

(B) notifications of a change in pharmacist-in-charge of a pharmacy; and

(C) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs, medication, devices, or other materials used in diagnosis or treatment of injury, illness, and disease.

(f) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for invoices and financial data shall comply with the following procedures.

(1) Controlled substance records. Invoices and financial data for controlled substances may be maintained at a central location provided the following conditions are met.

(A) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of the Drug Enforcement Administration as required by Title 21, Code of Federal Regulations, §1304.04(a), and submits a copy of this written notification to the Texas State Board of Pharmacy. Unless the registrant is informed by the divisional director of the Drug Enforcement Administration that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director.

(B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this paragraph.

(C) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the pharmacy.

(2) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location.

(3) Access to records. If the records are kept on microfilm, computer media, or in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records.

(4) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy location within two business days of written request of a board agent or any other authorized official.

§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. 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) Act--The Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Occupations Code, as amended.

(2) Ambulatory surgical center (ASC)--A freestanding facility that is licensed by the Texas Department of State Health Services to provide surgical services to patients who do not require overnight hospital care.

(3) Automated drug dispensing system--An automated device that measures, counts, and/or packages a specified quantity of dosage units for a designated drug product.

(4) Board--The Texas State Board of Pharmacy.

(5) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the ASC in areas that pertain to the practice of pharmacy.

(6) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug immediate precursor, or other substance included in Schedule I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(7) Direct copy--Electronic copy or carbonized copy of a medication order including a facsimile (FAX), tele-autograph, or a copy transmitted between computers.

(8) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(9) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(10) Downtime--Period of time during which a data processing system is not operable.

(11) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(12) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other ASC department (excluding the pharmacy) for the purpose of administration to a patient of the ASC.

(13) Formulary--List of drugs approved for use in the ASC by an appropriate committee of the ambulatory surgical center.

(14) Hard copy--A physical document that is readable without the use of a special device (i.e., cathode ray tube (CRT), microfiche reader, etc.).

(15) 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 federal Food and Drug Administration.

(16) 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.

(17) 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.

(18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other areas or departments of the ASC, or dispensed to an ultimate user or his or her agent.

(19) 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.

(20) Prescription drug order--

(A) A written order from a practitioner or 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.

(21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(22) Part-time pharmacist--A pharmacist who works less than full-time.

(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.

(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.

(25) Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and Safety Code, Chapter 481, as amended.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. Each ambulatory surgical center 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.

(B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following:

(i) establishment of specifications for procurement and storage of all materials, including drugs, chemicals, and biologicals;

(ii) participation in the development of a formulary for the ASC, subject to approval of the appropriate committee of the ASC;

(iii) distribution of drugs to be administered to inpatients pursuant to an original or direct copy of the practitioner's medication order;

(iv) filling and labeling all containers from which drugs are to be distributed or dispensed;

(v) maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and inpatient care areas, 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 ASC;

(vi) records of all transactions of the ASC pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials;

(vii) participation in those aspects of the ASC's patient care evaluation program which relate to pharmaceutical material utilization and effectiveness;

(viii) participation in teaching and/or research programs in the ASC;

(ix) implementation of the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the ASC;

(x) effective and efficient messenger and delivery service to connect the ASC pharmacy with appropriate areas of the ASC on a regular basis throughout the normal workday of the ASC;

(xi) 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;

(xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this subsection; and

(xiii) maintenance of records in a data processing system such that the data processing system is in compliance with the requirements for a Class C (institutional) pharmacy located in a free-standing ASC.

(2) Consultant pharmacist.

(A) The consultant pharmacist may be the pharmacist-in-charge.

(B) A written contract shall exist between the ASC and any consultant pharmacist, and a copy of the written contract shall be made available to the board upon request.

(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. All pharmacists 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 pharmacists engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(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).

(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 non-sterile and sterile preparations pursuant to medication orders;

(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 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. 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.

(ii) Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding sterile preparations shall meet the training requirements specified in §291.131 of this title.

(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) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows:

(A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that 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.

(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) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern.

(D) Pharmacists. All pharmacists shall wear an identification tag or badge that 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).

(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.

(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.

(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 of this title.

(K) An ASC pharmacy engaged in the compounding of sterile pharmaceuticals shall comply with the provisions of §291.133 of this title.

(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 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).

(2) Environment.

(A) General requirements.

(i) Each ambulatory surgical center shall have a designated work area separate from patient areas, and which shall have space adequate for the size and scope of pharmaceutical services and shall have adequate space and security for the storage of drugs.

(ii) The ASC pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

(B) Special requirements.

(i) The ASC pharmacy shall have locked storage for Schedule II controlled substances and other controlled drugs requiring additional security.

(ii) The ASC pharmacy shall have a designated area for the storage of poisons and externals separate from drug storage areas.

(C) Security.

(i) Only authorized personnel may have access to storage areas for prescription drugs and/or devices.

(ii) All storage areas for prescription drugs and/or devices shall be locked by key or combination, so as to prevent access by unauthorized personnel.

(iii) The pharmacist-in-charge shall consult with ASC personnel with respect to security of the drug storage areas, including provisions for adequate safeguards against theft or diversion of prescription drugs and/or devices.

(3) Equipment and supplies. Ambulatory surgical centers supplying drugs for postoperative use shall have the following equipment and supplies:

(A) typewriter or comparable equipment; and

(B) adequate supply of child-resistant, moisture-proof, and light-proof containers;

(C) adequate supply of prescription labels and other applicable identification labels;

(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, 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) 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.

(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) Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug.

(vi) 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) Floor stock. In facilities using a floor stock method of drug distribution, the following is applicable for removing drugs or devices in the absence of a pharmacist.

(A) Prescription drugs and devices may be removed from the pharmacy only in the original manufacturer's container or prepackaged container.

(B) Only a designated licensed nurse or practitioner may remove such drugs and devices.

(C) A record shall be made at the time of withdrawal by the authorized person removing the drug or device; the record shall contain the following information:

(i) name of the drug, strength, and dosage form;

(ii) quantity removed;

(iii) location of floor stock;

(iv) date and time; and

(v) signature or electronic signature of person making the withdrawal.

(D) A pharmacist shall verify the withdrawal according to the following schedule.

(i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as practical, but in no event more than 72 hours from the time of such withdrawal.

(ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after a reasonable interval, but in no event may such interval exceed seven days.

(8) Policies and procedures. Written policies and procedures for a drug distribution system, appropriate for the ambulatory surgical center, shall be developed and implemented by the pharmacist-in-charge with the advice of the appropriate committee. The written policies and procedures for the drug distribution system shall include, but not be limited to, procedures regarding the following:

(A) controlled substances;

(B) investigational drugs;

(C) prepackaging and manufacturing;

(D) medication errors;

(E) orders of physician or other practitioner;

(F) floor stocks;

(G) adverse drug reactions;

(H) drugs brought into the facility by the patient;

(I) self-administration;

(J) emergency drug tray;

(K) formulary, if applicable;

(L) drug storage areas;

(M) drug samples;

(N) drug product defect reports;

(O) drug recalls;

(P) outdated drugs;

(Q) preparation and distribution of IV admixtures;

(R) procedures for supplying drugs for postoperative use, if applicable;

(S) use of automated drug dispensing systems; and

(T) use of data processing systems.

(9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall be supplied according to the following procedures.

(A) Drugs may only be supplied to patients who have been admitted to the ambulatory surgical center.

(B) Drugs may only be supplied in accordance with the system of control and accountability established for drugs supplied from the ambulatory surgical center; such system shall be developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.

(C) Only drugs listed on the approved postoperative drug list may be supplied; such list shall be developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the nature and type to meet the immediate postoperative needs of the ambulatory surgical center patient.

(D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including necessary auxiliary labels) by the pharmacy, provided, however that topicals and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-hour supply.

(E) At the time of delivery of the drug, the practitioner shall complete the label, such that the prescription container bears a label with at least the following information:

(i) date supplied;

(ii) name of practitioner;

(iii) name of patient;

(iv) directions for use;

(v) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

(vi) unique identification number.

(F) After the drug has been labeled by the practitioner, the practitioner or a licensed nurse under the supervision of the practitioner shall give the appropriately labeled, prepackaged medication to the patient.

(G) A perpetual record of drugs which are supplied from the ASC shall be maintained which includes:

(i) name, address, and phone number of the facility;

(ii) date supplied;

(iii) name of practitioner;

(iv) name of patient;

(v) directions for use;

(vi) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

(vii) unique identification number.

(H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall review the records at least once every seven days.

(e) Records.

(1) Maintenance of records.

(A) Every inventory or other record required to be kept under the provisions of this section (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 a mutually agreeable 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) Outpatient records.

(A) Only a registered pharmacist may receive, certify, and receive prescription drug orders.

(B) Outpatient records shall be maintained as provided in §291.34 and §291.35 of this title contained in Community Pharmacy (Class A).

(C) Outpatient prescriptions, including, but not limited to, discharge prescriptions, that are written by the practitioner, must be written on a form which meets the requirements of the Act, §562.006. Medication order forms or copies thereof do not meet the requirements for outpatient forms.

(D) Controlled substances listed in Schedule II must be written on an electronic prescription form in accordance with the Texas Controlled Substances Act, §481.075, and rules promulgated pursuant to the Texas Controlled Substances Act, unless exempted by the Texas Controlled Substances Rules, 37 TAC §13.74. Outpatient prescriptions for Schedule II controlled substances that are exempted from the official prescription requirement must be manually signed by the practitioner.

(3) Inpatient records.

(A) Each original medication order or set of orders issued together shall bear the following information:

(i) patient name;

(ii) drug name, strength, and dosage form;

(iii) directions for use;

(iv) date; and

(v) signature or electronic signature of the practitioner or that of his or her authorized agent, defined as a licensed nurse employee or consultant/full or part-time pharmacist of the ASC.

(B) Original medication orders shall be maintained with the medication administration record in the medical records of the patient.

(C) Controlled substances records shall be maintained as follows.

(i) All records for controlled substances shall be maintained in a readily retrievable manner.

(ii) Controlled substances records shall be maintained in a manner to establish receipt and distribution of all controlled substances.

(D) Records of controlled substances listed in Schedule II shall be maintained as follows.

(i) Records of controlled substances listed in Schedule II shall be maintained separately from records of controlled substances in Schedules III, IV, and V, and all other records.

(ii) An ASC pharmacy shall maintain a perpetual inventory of any controlled substance listed in Schedule II.

(iii) Distribution records for Schedule II - V controlled substances floor stock shall include the following information:

(I) patient's name;

(II) practitioner who ordered drug;

(III) name of drug, dosage form, and strength;

(IV) time and date of administration to patient and quantity administered;

(V) signature or electronic signature of individual administering controlled substance;

(VI) returns to the pharmacy; and

(VII) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(E) Floor stock records shall be maintained as follows.

(i) Distribution records for Schedules III - V controlled substances floor stock shall include the following information:

(I) patient's name;

(II) practitioner who ordered controlled substance;

(III) name of controlled substance, dosage form, and strength;

(IV) time and date of administration to patient;

(V) quantity administered;

(VI) signature or electronic signature of individual administering drug;

(VII) returns to the pharmacy; and

(VIII) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(ii) The record required by clause (i) of this subparagraph shall be maintained separately from patient records.

(iii) A pharmacist shall review distribution records with medication orders on a periodic basis to verify proper usage of drugs, not to exceed 30 days between such reviews.

(F) General requirements for records maintained in a data processing system are as follows.

(i) If an ASC pharmacy's data processing system is not in compliance with the board's requirements, the pharmacy must maintain a manual recordkeeping system.

(ii) Requirements for backup systems. The facility shall maintain a backup copy of information stored in the data processing system using disk, tape, or other electronic backup system and update this backup copy on a regular basis to assure that data is not lost due to system failure.

(iii) Change or discontinuance of a data processing system.

(I) Records of distribution and return for all controlled substances, nalbuphine (Nubain), and tripelennamine (PBZ). A pharmacy that changes or discontinues use of a data processing system must:

(-a-) transfer the records to the new data processing system; or

(-b-) purge the records to a printout which contains the same information as required on the audit trail printout as specified in subparagraph (G)(ii) of this paragraph. The information on this printout shall be sorted and printed by drug name and list all distributions/returns chronologically.

(II) Other records. A pharmacy that changes or discontinues use of a data processing system must:

(-a-) transfer the records to the new data processing system; or

(-b-) purge the records to a printout which contains all of the information required on the original document.

(III) Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(iv) Loss of data. The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(G) Data processing system maintenance of records for the distribution and return of all controlled substances, nalbuphine (Nubain), or tripelennamine (PBZ) to the pharmacy.

(i) Each time a controlled substance, nalbuphine (Nubain), or tripelennamine (PBZ) is distributed from or returned to the pharmacy, a record of such distribution or return shall be entered into the data processing system.

(ii) The data processing system shall have the capacity to produce a hard-copy printout of an audit trail of drug distribution and return for any strength and dosage form of a drug (by either brand or generic name or both) during a specified time period. This printout shall contain the following information:

(I) patient's name and room number or patient's facility identification number;

(II) prescribing or attending practitioner's name;

(III) name, strength, and dosage form of the drug product actually distributed;

(IV) total quantity distributed from and returned to the pharmacy;

(V) if not immediately retrievable via CRT display, the following shall also be included on the printout:

(-a-) prescribing or attending practitioner's address; and

(-b-) practitioner's DEA registration number, if the medication order is for a controlled substance.

(iii) An audit trail printout for each strength and dosage form of these drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the facility. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

(iv) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law enforcement or regulatory agencies.

(H) Failure to maintain records. Failure to provide 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.

(I) Data processing system downtime. In the event that an ASC pharmacy which uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for on-line data entry as soon as the system is available for use again.

(4) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practi-

tioner, another pharmacy, or other registrant, without being registered to distribute, under the following conditions.

(A) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to dispense that controlled substance.

(B) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled substances.

(C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained which indicates:

(i) the actual date of distribution;

(ii) the name, strength, and quantity of controlled substances distributed;

(iii) the name, address, and DEA registration number of the distributing pharmacy; and

(iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

(D) If the distribution is for a Schedule I or II controlled substance, the following is applicable.

(i) The pharmacy, practitioner, or other registrant who is receiving the controlled substances shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222C) to the distributing pharmacy.

(ii) The distributing pharmacy shall:

(I) complete the area on the DEA order form (DEA 222C) titled "To Be Filled in by Supplier";

(II) maintain Copy 1 of the DEA order form (DEA 222C) at the pharmacy for two years; and

(III) forward Copy 2 of the DEA order form (DEA 222C) to the divisional office of the Drug Enforcement Administration.

(5) Other records. Other records to be maintained by the pharmacy include:

(A) a permanent log of the initials or identification codes which will identify each pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified, i.e., identical initials or identification codes cannot be used;

(B) Copy 3 of DEA order form (DEA 222C), which has been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents;

(C) a hard copy of the power of attorney to sign DEA 222C order forms (if applicable);

(D) suppliers' invoices of dangerous drugs and controlled substances; a pharmacist shall verify that the controlled drugs listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances;

(E) supplier's credit memos for controlled substances and dangerous drugs;

(F) a hard copy of inventories required by §291.17 of this title (relating to Inventory Requirements) except that a perpetual inventory of controlled substances listed in Schedule II may be kept in a data processing system if the data processing system is capable of producing a hard copy of the perpetual inventory on-site;

(G) hard-copy reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency;

(H) a hard-copy Schedule V nonprescription register book;

(I) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(J) a hard copy of any notification required by the Texas Pharmacy Act or these rules, including, but not limited to, the following:

(i) reports of theft or significant loss of controlled substances to DEA, DPS, and the board;

(ii) notification of a change in pharmacist-in-charge of a pharmacy; and

(iii) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and disease.

(6) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for invoices and financial data shall comply with the following procedures.

(A) Controlled substance records. Invoices and financial data for controlled substances may be maintained at a central location provided the following conditions are met.

(i) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of the Drug Enforcement Administration as required by the Code of Federal Regulations, Title 21, §1304(a), and submits a copy of this written notification to the Texas State Board of Pharmacy. Unless the registrant is informed by the divisional director of the Drug Enforcement Administration that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director.

(ii) The pharmacy maintains a copy of the notification required in this subparagraph.

(iii) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the pharmacy.

(B) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location.

(C) Access to records. If the records are kept on microfilm, computer media, or in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records.

(D) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy location within two business days of written request of a board agent or any other authorized official.

(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 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. CLINIC PHARMACY (CLASS D)

22 TAC §291.92

The Texas State Board of Pharmacy adopts amendments to §291.92, concerning Personnel without changes to the proposed text as published in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3493).

The amendments clarify the responsibilities of owners of Class D pharmacies

No comments were received regarding the proposal.

The amendments are adopted 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: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

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 August 29, 2007.

TRD-200703987
Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Effective date: September 18, 2007
Proposal publication date: June 15, 2007
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SUBCHAPTER F. NON-RESIDENT PHARMACY (CLASS E)

22 TAC §291.104, §291.105

The Texas State Board of Pharmacy adopts amendments to §291.104, concerning Operational Standards and §291.105, concerning Records with changes to the proposed text as published in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3493). The changes to the sections are described in this preamble.

The amendments to §291.104 update references to other rules in this chapter and the amendments to §291.105 require pharmacies to provide the board or its representative with records in electronic format, if the records are maintained in an electronic format.

NACDS commented that the amendments to §291.105, requiring pharmacies to provide the Board or its representatives with records in electronic format, would increase costs to pharmacies and would expend hours trying to adapt the pharmacies computer system to meet the Board's needed format. The Board amended the proposed language to reflect that the records must be provided in a mutually agreeable format.

The amendments are adopted 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: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.104. Operational Standards.

(a) Licensing requirements.

(1) A Class E pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board.

(2) On initial application, the pharmacy shall follow the procedures specified in §291.1 of this title (relating to Pharmacy License Application) and the provide the following additional information specified in §560.052(c) and (f) of the Act (relating to Qualifications):

(A) evidence that the applicant holds a pharmacy license, registration, or permit issued by the state in which the pharmacy is located;

(B) the name of the owner and pharmacist-in-charge of the pharmacy for service of process;

(C) evidence of the applicant's ability to provide to the board a record of a prescription drug order dispensed by the applicant to a resident of this state not later than 72 hours after the time the board requests the record;

(D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read and understands the laws and rules relating to a Class E pharmacy;

(E) proof of creditworthiness; and

(F) an inspection report issued not more than two years before the date the license application is received and conducted by the pharmacy licensing board in the state of the pharmacy's physical location.

(i) A Class E pharmacy may submit an inspection report issued by an entity other than the pharmacy licensing board of the state in which the pharmacy is physically located if the state's licensing board does not conduct inspections as follows:

(I) an individual approved by the board who is not employed by the pharmacy but acting as a consultant to inspect the pharmacy;

(II) an agent of the National Association of Boards of Pharmacy;

(III) an agent of another State Board of Pharmacy; or

(IV) an agent of an accrediting body, such as the Joint Commission on Accreditation of Healthcare Organizations.

(ii) The inspection must be substantively equivalent to an inspection conducted by the board.

(3) On renewal of a license, the pharmacy shall complete the renewal application provided by the board and, as specified in §561.031 of the Act, provide an inspection report issued not more than three years before the date the renewal application is received and conducted by the pharmacy licensing board in the state of the pharmacy's physical location.

(A) A Class E pharmacy may submit an inspection report issued by an entity other than the pharmacy licensing board of the state in which the pharmacy is physically located if the state's licensing board does not conduct inspections as follows:

(i) an individual approved by the board who is not employed by the pharmacy but acting as a consultant to inspect the pharmacy;

(ii) an agent of the National Association of Boards of Pharmacy;

(iii) an agent of another State Board of Pharmacy; or

(iv) an agent of an accrediting body, such as the Joint Commission on Accreditation of Healthcare Organizations.

(B) The inspection must be substantively equivalent to an inspection conducted by the board.

(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).

(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.

(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.

(7) A Class E pharmacy shall notify the board in writing within ten days of closing.

(8) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(9) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.

(10) The board may grant an exemption from the licensing requirements of this Act on the application of a pharmacy located in a state of the United States other than this state that restricts its dispensing of prescription drugs or devices to residents of this state to isolated transactions.

(11) A Class E pharmacy engaged in the centralized dispensing of prescription drug or medication orders shall comply with the provisions of §291.125 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 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 shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(14) A Class E (Non-Resident) pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(b) Prescription dispensing and delivery.

(1) General.

(A) All prescription drugs and/or devices shall be dispensed and delivered safely and accurately as prescribed.

(B) The pharmacy shall maintain adequate storage or shipment containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of packaging material and devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

(C) The pharmacy shall utilize a delivery system which is designed to assure that the drugs are delivered to the appropriate patient.

(D) All Pharmacists shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order they dispense. If the pharmacist questions the accuracy or authenticity of a prescription drug order, he/she shall verify the order with the practitioner prior to dispensing.

(E) Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound professional judgment, that the pre-

scription is a valid prescription. A pharmacist may not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid patient-practitioner relationship.

(F) Subparagraph (E) of this paragraph does not prohibit a pharmacist from dispensing a prescription when a valid patient-practitioner relationship is not present in an emergency situation (e.g. a practitioner taking calls for the patient's regular practitioner).

(2) Drug regimen review.

(A) For the purpose of promoting therapeutic appropriateness, a pharmacist shall prior to or at the time of dispensing a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant:

(i) inappropriate drug utilization;

(ii) therapeutic duplication;

(iii) drug-disease contraindications;

(iv) drug-drug interactions;

(v) incorrect drug dosage or duration of drug treatment;

(vi) drug-allergy interactions; and

(vii) clinical abuse/misuse.

(B) Upon identifying any clinically significant conditions, situations, or items listed in subparagraph (A) of this paragraph, the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner. The pharmacist shall document such occurrences.

(3) 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 orally 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) 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.

(E) 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 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)."

(F) 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).

(G) Upon delivery of a refill prescription, a pharmacist shall ensure that the patient or patient's agent is offered information about the refilled prescription and that a pharmacist is available to discuss the patient's prescription and provide information.

(H) 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.

(c) Generic Substitution. Unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located:

(1) a pharmacist in a Class E pharmacy may dispense a generically equivalent drug product if:

(A) the generic product costs the patient less than the prescribed drug product;

(B) the patient does not refuse the substitution; and

(C) the prescribing practitioner authorizes the substitution of a generically equivalent product; or

(D) the practitioner or practitioner's agent does not clearly indicate that the oral or electronic prescription drug order shall be dispensed as ordered; and

(2) Pharmacists shall use as a basis for the determination of generic equivalency as defined in the Subchapter A, Chapter 562 of the Act, the following.

(A) For drugs listed in the publication, pharmacists shall use Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) and current supplements published by the Federal Food and Drug Administration, within the limitations stipulated in that publication, to determine generic equivalency. Pharmacists may only substitute products that are rated therapeutically equivalent in the Orange Book and have an "A" rating. "A" rated drug products include but are not limited to, those designated AA, AB, AN, AO, AP, or AT in the Orange Book.

(B) For drugs not listed in the Orange Book, pharmacists shall use their professional judgment to determine generic equivalency.

(3) The pharmacy must include on the prescription order form completed by the patient or the patient's agent information that clearly and conspicuously:

(A) states that if a less expensive generically equivalent drug is available for the brand prescribed, the patient or the patient's agent may choose between the generically equivalent drug and the brand prescribed; and

(B) allows the patient or the patient's agent to indicate the choice of the generically equivalent drug or the brand prescribed.

(d) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response to the one prescribed shall not be made without prior approval of the prescribing practitioner. This subsection does not apply to generic substitution. For generic substitution, see the requirements of subsection (c) of this section.

(1) The patient shall be notified of the therapeutic drug interchange prior to, or upon delivery, of the dispensed prescription to the patient. Such notification shall include:

(A) a description of the change;

(B) the reason for the change;

(C) whom to notify with questions concerning the change; and

(D) instructions for return of the drug if not wanted by the patient.

(2) The pharmacy shall maintain documentation of patient notification of therapeutic drug interchange which shall include:

(A) the date of the notification;

(B) the method of notification;

(C) a description of the change; and

(D) the reason for the 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 is making the transfer request on behalf of the patient.

(f) Prescriptions for Schedule II controlled substances. 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 who dispenses a prescription for a Schedule II controlled substance issued on a Texas Official Prescription Form shall:

(1) mail a copy of the form to the Texas Department of Public Safety, Electronic Prescription Section, P.O. Box 4087, Austin, Texas 78773 within 30 days of dispensing; or

(2) electronically send the prescription information to the Texas Department of Public Safety per their requirements for electronic submissions within 30 days of dispensing.

§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 a mutually agreeable 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) 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;

(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.

(b) Civil litigation and complaint records. A Class E pharmacy shall keep a permanent record of:

(1) any civil litigation commenced against the pharmacy by a Texas resident; and

(2) complaints that arise out of a prescription for a Texas resident lost during delivery.

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 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 adopts 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 §291.133, concerning Pharmacies Compounding Sterile Preparations. New §§291.20, 291.121, 291.123, 291.125, 291.127, and 291.129 are adopted without changes to the proposed text as published in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3494). New §291.131 and §291.133 are adopted with changes to the proposed text and the changes are described in this preamble.

New §291.120 provides the purpose of the new subchapter to reorganize rules for all pharmacy services which were previously located in the rules pertaining to specific classes of pharmacy in a central location. New §291.121 contains the requirements for remote pharmacy services previously found in §291.20 which is adopted for repeal published elsewhere in this issue of the *Texas Register*. New §291.123 provides the requirements for Central Prescription Drug Order or Medication Order Processing previously found in §291.38 which is adopted for repeal published elsewhere in this issue of the *Texas Register*. New §291.125 provides the requirements for Centralized Prescription Dispensing previously found in §291.37 which is adopted for repeal published elsewhere in this issue of the *Texas Register*. New §291.127 provides the requirements for Emergency Remote Pharmacy License previously found in §291.13 which is adopted for repeal published elsewhere in this issue of the *Texas Register*. New §§291.121, 291.123, 291.125, and 291.127 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 provides 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 outlines operating standards for pharmacies that compound non-sterile preparations, implement the recommendations of the Texas State Board of Pharmacy's 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 Senate Bill 492 passed during the 79th Regular Session of the Texas Legislature regarding compounding. New §291.133 outlines operating standards for pharmacies that compound sterile preparations, implement the recommendations of the Texas State Board of Pharmacy's 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 Senate Bill 492 passed during the 79th Regular Session of the Texas Legislature regarding compounding.

The Texas Society of Health-System Pharmacists (TSHP) commented on §291.121 with regard to the applications for pharmacies using automated pharmacy systems. TSHP recommended that the resubmittal of applications every two years was not necessary and that Class C pharmacies providing remote order entry to facilities under common ownership should be exempted from the application requirements. The Board disagrees with these comments because the amendments do not apply to Class C pharmacies as interpreted by TSHP.

The National Association of Chain Drug Stores (NACDS) commented that §291.129, that requires a prescription entered into a pharmacy's data processing system be verified by a pharmacist at the time of data entry, would be burdensome and disruptive to pharmacy workflow. The Board disagrees with this comment and believes that prescriptions must be checked at the time of data entry in order to ensure that patients receive accurately dispensed prescriptions.

TSHP commented that the definition of hot water in §291.131 should be consistent with the requirements used for hospital construction standards by the Texas Department of State Health Services (DSHS). DSHS requires hot water to be between 105 and 120 degrees Fahrenheit. The Board agrees with this comment and amended the proposed language to reflect that hot water be a minimum of 105 degrees Fahrenheit.

NACDS commented that §291.131(c)(4) should be changed to allow pharmacists to certify the required training for individuals involved in the compounding of non-sterile preparations. The Board disagrees with this comment and requires the documentation of training to ensure that individual involved in compounding are adequately trained.

TSHP provided a general comment regarding §291.133 and the references to continuing education provided by "approved" providers. The more contemporary term is "accredited" providers. The Board agrees with the comment and amended the rules as necessary to reflect the change.

TSHP commented that the definition of buffer area found in §291.133(a)(11) be amended to include buffer zone. The Board agrees with this comment and amended the rules to reflect the change.

TSHP commented that the definition of clean room found in §291.133(a)(12) be amended to include controlled area. The Board agrees with this comment and amended the rules to reflect the change.

TSHP commented that the definition of hot water found in §291.133(a)(21) should be consistent with the requirements used for hospital construction standards by the Texas Department of State Health Services (DSHS). DSHS requires hot water to be between 105 and 120 degrees Fahrenheit. The Board agrees with this comment and amended the proposed language to reflect that hot water be a minimum of 105 degrees Fahrenheit.

TSHP commented that the definition of Preparation or Compounded Sterile Preparation be amended by deleting the statement "the article may or may not contain sterile products." The Board agrees with this comment and deleted the statement from the rule.

TSHP commented that the word "products" in the definition of quality assurance in §291.133(a)(36) be changed to "preparations" to be consistent with the rest of the rule. The board agrees with this comment and amended the rules to reflect the change.

TSHP commented that the reference to pharmacist found in §291.133(c)(1)(B)(II) should be changed to personnel which would also include pharmacy technicians and pharmacy technician trainees. The Board agrees with this comment and amended the rules to reflect the change.

TSHP commented that the word "continuing" education found in §291.133(c)(1)(B)(II) and (4)(D) be deleted. The Board agrees with this comment and amended the rules to reflect the change.

Apothecure commented that §291.133(c)(2)(E) be change to require pharmacists to be available during normal business hours and not 24 hours a day. The Board disagrees with this comment and require that for patient safety, a pharmacist must be available by phone or pager in order to assist patients.

U.S. Oncology commented that §291.133(d)(4) be deleted from the proposed rules. The Board disagrees with this comment in that it clarifies the requirements for cytoxic drugs and these are not considered immediate use drugs based on the definitions.

TSHP commented that the reference to a designated room found in §291.133(d)(5)(A)(i) be changed to a clean room/controlled area. The Board agrees with this comment and amended the rules to reflect the change.

U.S. Oncology commented that §291.133(d)(5)(A)(i)(X) should reference an ante-zoon. The Board agrees with this comment and amended the rules to reflect the change.

U.S. Oncology commented that §291.133(d)(5)(A)(i)(XI)(-c-) be deleted. The Board agrees with the comment and amended the rules to reflect the change.

TSHP, Texas Oncology, and U.S. Oncology commented that the requirements for compounding cytotoxic preparations found in §291.133 were contradictory and should be removed. The Board agrees with the comment and amended the rules to reflect the change.

TSHP commented that the labeling requirements found in §291.133(d)(7)(A)(ii) should not be applicable to inpatient medication orders. The Board agrees with the comment and amended the rules to reflect the change.

TSHP commented that the beyond use date referenced in §291.133(d)(7)(A)(iii) was not consistent with the definition of beyond use date found elsewhere in this section. The Board agrees with the comment and amended the rules to reflect the change.

TSHP commented that §291.133(d)(8) should not apply to medication orders. The Board agrees with the comment and amended the rules to reflect the change.

TSHP commented that §291.133(d)(9)(B) should not apply to inpatient medication orders. The Board agrees with the comment and deleted the requirement.

Stephanie Erwin, R.Ph., commented that the requirement for non-shedding disposable gowns in §291.133(d)(11)(C)(iv)(III) be changed to allow for clean and sanitized gowns. The Board agrees with the comment and amended the rules to allow for "clean non-shedding" gowns to be used.

Texas Oncology commented on §291.133(d)(11)(C)(iv)(V) with regard to gloves being required to sterilized with disinfectant even if the pharmacy is using sterile gloves. The Board agrees with the comment and amended the rules to not require pharmacies using sterile gloves use a disinfectant except whenever non-sterile surfaces are touched.

TSHP commented that the recordkeeping requirements for patient specific orders should not include medication orders. The Board agrees with this comment and deleted the reference to medication orders.

The new rules are adopted 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 by the new rules: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§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 §562.154 or Chapter 563 of the Occupations Code.

(4) Hot water-The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees 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 §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 §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, or Buffer Zone--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 or controlled area--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 §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 a minimum of 105 degrees F (41 degrees 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 §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.

(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 preparations lead to preparations 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 personnel involved in compounding sterile preparations obtain continuing education appropriate for the type of compounding done by the personnel;

(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 accredited 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 accredited 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 accredited 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, 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) Prior to September 1, 2008.

(i) Controlled area.

(I) Low and Medium Risk Preparations. The pharmacy shall have a designated controlled area for the compounding of sterile pharmaceuticals that is functionally separate from areas for the preparation of non-sterile pharmaceuticals and is constructed to minimize the opportunities for particulate and microbial contamination. This controlled area for the preparation of sterile pharmaceuticals shall:

(-a-) have a controlled environment that is aseptic or contains an aseptic environmental control device(s). If the aseptic environmental control device is located within the controlled area, the controlled area must extend a minimum of six feet from the device and clearly marked to identify the separation between the controlled and non-controlled area;

(-b-) be clean, well lighted, and of sufficient size to support sterile compounding activities;

(-c-) be used only for the compounding of sterile pharmaceuticals;

(-d-) be designed to avoid outside traffic and air flow;

(-e-) be designed such that hand sanitizing and gowning occurs outside the controlled area but is accessible without use of the hands of the compounding personnel;

(-f-) have non-porous and washable floors or floor covering to enable regular disinfection;

(-g-) be ventilated in a manner not interfering with aseptic environmental control conditions;

(-h-) have walls, ceilings, and fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices, and nonshedding. (acoustical ceiling tiles that are coated with an acrylic paint are acceptable);

(-i-) have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning; and

(-j-) contain only the appropriate compounding supplies and not be used for bulk storage for supplies and materials. Objects that shed particles may not be brought into the controlled area.

(II) High-risk Preparations. In addition to the requirements in subclause (I) of this clause, when high-risk preparations are compounded, the aseptic environment control device(s) shall be located in a controlled area that maintains at least an ISO Class 8 (formerly Class 100,000) environment.

(ii) Aseptic environment control device(s). The pharmacy shall prepare sterile pharmaceuticals in an appropriate aseptic environmental control device(s) or area, such as a laminar air flow hood, biological safety cabinet, clean room which is capable of maintaining at least ISO Class 5 (formerly Class 100) conditions during normal activity, or other aseptic environmental control devices that produce ISO Class 5 (formerly Class 100) environmental conditions or better. The aseptic environmental control device(s) shall:

(I) 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 or when it is relocated; and

(II) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures, and the inspection and/or replacement date documented.

(iii) Automated compounding or counting device. If automated compounding or counting devices are used, the pharmacy shall have a method to calibrate and verify the accuracy of automated compounding or counting devices used in aseptic processing and document the calibration and verification on a routine basis.

(B) Low and Medium Risk Preparations.

(i) Effective September 1, 2008, a pharmacy that prepares low- and medium-risk preparations shall have a clean room/controlled area for the compounding of sterile preparations that is constructed to minimize the opportunities for particulate and microbial contamination. The clean room/controlled area 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/ante-zone 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 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.

(-d-) 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.

(C) High-risk Preparations. In addition to the requirements in subparagraph (B) 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.

(D) 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.

(E) Cytotoxic drugs. If the preparation is cytotoxic, the following is also 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. Cytotoxic drugs must be prepared in a Class II or III vertical flow biological safety cabinet or compounding aseptic isolator.

(F) 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.

(G) 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.

(H) 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) For outpatient prescription orders only, 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. 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 for prescription drug orders only. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing a prescription drug order. 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 for sterile preparations compounded pursuant to prescription drug orders must be met.

(A) 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).

(B) 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:

(I) safeguards against microbial contamination, including aseptic techniques for compounding intravenous admixtures and aseptic techniques for injecting additives to premixed intravenous solutions;

(II) appropriate storage methods, including storage durations for sterile pharmaceuticals and expirations of self-mixed solutions;

(III) handling and disposition of premixed and self-mixed intravenous admixtures; and

(IV) proper disposition of intravenous admixture compounding supplies such as syringes, vials, ampules, and intravenous solution containers.

(C) 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).

(D) 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.

(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 clean non-shedding 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, either those which are sterile or have been disinfected by applying 70% IPA or appropriate disinfectant to all contact surface areas and allowed to dry, that form a continuos barrier with the gown shall be the last item donned before compounding begins. 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% nonsterile 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 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 §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 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 August 29, 2007.

TRD-200703989
Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Effective date: September 18, 2007
Proposal publication date: June 15, 2007
For further information, please call: (512) 305-8028

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CHAPTER 295. PHARMACISTS

22 TAC §295.5

The Texas State Board of Pharmacy adopts amendments to §295.5, concerning Pharmacist License or Renewal Fees. The amendments are adopted with changes to the proposed text as published in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3531). The changes to the section are described in this preamble.

The amendments to §295.5 will raise pharmacist license fees based on increased expenses. The Board was able to substantially reduce the proposed fee increase for all licensees, including reducing the proposed pharmacist initial and renewal fees from $239, to $214, based on the final appropriations to the agency that were approved by the Texas Legislature.

No comments were received regarding the proposal.

The amendments are adopted under §§551.002, 554.051, 554.006, and 564.051 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 Board interprets §564.006 as authorizing the agency to adopt rules to establish reasonable and necessary fees to produce sufficient revenue to cover the cost of administering the Act. The Board interprets §564.051 as authorizing the agency to collect a surcharge to fund a program to aid impaired pharmacists and pharmacy students.

The statutes affected by the amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§295.5. Pharmacist License or Renewal Fees.

(a) Biennial Registration. The Texas State Board of Pharmacy shall require biennial renewal of all pharmacist licenses provided under the Pharmacy Act, §559.002.

(b) Initial License Fee.

(1) The fee for the initial license shall be $214 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 surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act, §564.051;

(B) $10 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(C) $5 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, Occupations Code.

(3) New pharmacist licenses shall be assigned an expiration date and initial fee shall be prorated based on the assigned expiration date.

(c) Renewal Fee.

(1) The fee for biennial renewal of a pharmacist license shall be $214 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 surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act, §564.051;

(B) $10 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(C) $2 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, Occupations Code.

(d) Exemption from fee. The license of a pharmacist who has been licensed by the Texas State Board of Pharmacy for at least 50 years or who is at least 72 years old shall be renewed without payment of a fee provided such pharmacist is not actively practicing pharmacy. The renewal certificate of such pharmacist issued by the board shall reflect an inactive status. A person whose license is renewed pursuant to this subsection may not engage in the active practice of pharmacy without first paying the renewal fee as set out in subsection (b) of this section.

(e) Duplicate or Amended Certificates.

(1) The fee for issuance of an amended pharmacist's license renewal certificate shall be $20.

(2) The fee for issuance of an amended license to practice pharmacy (wall certificate) only, or renewal certificate and wall certificate shall be $35.

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 August 29, 2007.

TRD-200703993
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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22 TAC §295.9

The Texas State Board of Pharmacy adopts amendments to §295.9, concerning Inactive License. The amendments are adopted without changes to the proposed text as published in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3531).

The amendments require pharmacists wanting to reactivate an inactive license to submit proof of completion of 30 hours of approved continuing education.

No comments were received regarding the proposal.

The amendments are adopted under §§551.002, 554.051, and 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 §554.001(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 §559.101 as authorizing the agency to adopt rules regarding inactive licenses.

The statutes affected by the amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

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 August 29, 2007.

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Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Effective date: September 18, 2007
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For further information, please call: (512) 305-8028

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CHAPTER 297. PHARMACY TECHNICIANS AND PHARMACY TECHNICIAN TRAINEES

22 TAC §297.3

The Texas State Board of Pharmacy adopts amendments to §297.3, concerning Registration Requirements. The amendments are adopted without changes to the proposed text as published in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3532).

The amendments will recognize the abbreviation "Ph.T.R." to be used by registered pharmacy technicians.

The Texas Society of Health-System Pharmacists submitted comments supporting the amendments.

The National Association of Chain Drug Stores submitted comments requesting that the Board allow pharmacy technicians who have submitted their registration materials to the Board be permitted to start work in a pharmacy while the Board process the application. The Board disagrees with this comment. The Board must ensure that individuals allowed to work in a pharmacy meet the qualifications and are safe to practice as pharmacy technicians. Allowing individuals to work in a pharmacy while the Board processes the registration application could potentially allow unqualified individuals to work in a pharmacy.

The amendments are adopted 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 §554.001(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 statutes affected by the amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

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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Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Effective date: September 18, 2007
Proposal publication date: June 15, 2007
For further information, please call: (512) 305-8028

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22 TAC §297.4

The Texas State Board of Pharmacy adopts amendments to §297.4, concerning Fees, with changes to the proposed text as published in the June 15, 2007, issue of the *Texas Register* (32 TexReg 3532). The changes to this section are described in this preamble.

The amendments will raise pharmacy technician registration fees based on increased expenses. The Board was able to substantially reduce the proposed fee increase for all licensees, including reducing the proposed pharmacy technician initial and renewal fees from $64 to $59, and $61 to $56, respectively, based on the final appropriations to the agency that were approved by the Texas Legislature.

No comments were received regarding the proposal.

The amendments are adopted under §§551.002, 554.051, 554.006, and 564.051 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 Board interprets §564.006 as authorizing the agency to adopt rules to establish reasonable and necessary fees to produce sufficient revenue to cover the cost of administering the Act.

The statutes affected by the amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§297.4. Fees.

(a) Pharmacy technician trainee. There shall be no fee for registration as a pharmacy technician trainee.

(b) Pharmacy technician.

(1) Biennial Registration. The board shall require biennial renewal of all pharmacy technician registrations provided under Chapter 568 of the Act.

(2) Initial Registration Fee.

(A) The fee for initial registration shall be $59 for a two year registration and is composed of the following fees:

(i) $51 for processing the application and issuance of the pharmacy technician registration as authorized by the Act, §568.005;

(ii) a $3 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(iii) $5 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, Occupations Code.

(B) The initial registration fee shall be prorated based on the assigned expiration date.

(3) Renewal Fee. The fee for biennial renewal of a pharmacy technician registration shall be $56 and is composed of the following:

(A) $51 for processing the application and issuance of the pharmacy technician registration as authorized by the Act, §568.005;

(B) a $3 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(C) $2 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, Occupations Code.

(c) Duplicate or Amended Certificates. The fee for issuance of a duplicate or amended pharmacy technician trainee registration certificate or pharmacy technician registration renewal certificate shall be $20.

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 August 29, 2007.

TRD-200703994
Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Effective date: October 1, 2007
Proposal publication date: June 15, 2007
For further information, please call: (512) 305-8028

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TITLE 31. NATURAL RESOURCES AND CONSERVATION

PART 10. TEXAS WATER DEVELOPMENT BOARD

CHAPTER 363. FINANCIAL ASSISTANCE PROGRAMS

SUBCHAPTER E. ECONOMICALLY DISTRESSED AREAS

DIVISION 1. ECONOMICALLY DISTRESSED AREAS PROGRAM

31 TAC §363.511

The Texas Water Development Board (board) adopts new 31 TAC §363.511 concerning temporary continuation of funding under the Economically Distressed Areas Program (EDAP) model subdivision Rules (model rules). Section 363.511 is adopted with changes to the proposed text as published in the July 13, 2007, *Texas Register* (32 TexReg 4329).

The rule implements Senate Bill 3, Article VI, 80th Legislature relating to compliance with the model rules.

In the past few years, issues related to local entities' understanding of and compliance with the model rules, along with the board's oversight of the model rules enforcement efforts by those entities, have caused worthwhile projects to be halted, project costs to increase, and, in some cases, homeowners to continue living without adequate water and wastewater service. Recent examples include the City of Laredo, the City of Odem, San Patricio County, and the City of Donna. New §363.511, based on the Legislative action in Senate Bill 3, ensures that existing EDAP projects may move forward while maintaining compliance with the model subdivision rules.

The board conducted a public hearing on the proposed rule on August 7, 2007, in room E1.012 Capitol Extension, 1400 N. Congress Ave., Austin, Texas. At the meeting, the board received oral comments from the Senate Committee on International Relations and Trade, the Secretary of State, and Texas Low Income Housing Information Services. Written comments were submitted by El Paso County and the Texas Commission on Environmental Quality. In addition, a public hearing was held on August 2, 2007, in room E1.012 Capitol Extension, 1400 N. Congress Ave., Austin, Texas, at which no comments were received. The comment period closed on August 13, 2007.

Two commenters recommended that the rule enumerate certain definitions and establish guidelines for the board in making determinations of what constitute sufficient safeguards and what actions are necessary and appropriate.

In developing the criteria suggested by the comments, the board tries to provide guidance while not limiting the options for an entity to demonstrate compliance going forward. Thus, the process envisioned by the rule is that the board will analyze the conditions that exist in the political subdivision at the time the request for temporary continuation of funding is made.

Safeguards include indications of both adoption and enforcement of the model rules. Adoption may mean adoption of the text of the model rules as contained in 31 TAC Chapter 364, in an open meeting with a quorum present, after due notice, in accordance with the Texas Open Meetings Act, Tex. Gov't Code Chapter 551. Adoption of the model rules can also mean modification of the political subdivision's existing residential subdivision rules to include the elements of the model rules contained in 31 TAC Chapter 364. Adoption of the model rules is evidenced by signed and sealed copies of the required notice, resolution, and the adopted rules. *The board accepts the comments and has added clarifying language.*

One commenter suggested that having determining factors for compliance would be helpful so that developers and political subdivisions would know what actions are needed to maintain compliance.

Political subdivisions demonstrate compliance with the model rules in a number of ways. For example, the political subdivision may present approved residential subdivisions plats that conform to the platting requirements of the model rules. In situations where the developer or subdivider is not meeting the requirements for development of residential subdivisions in political subdivisions that have adopted the model rules, deficiencies may be shown by the existence of plats that are approved without the platting requirements set out in the model rules being in place on the plat, by the purchase or sale of residential subdivision property that lacks adequate water or wastewater facilities, or by violations under the Local Gov't Code Chapters 212 or 232. In such cases, enforcement may mean taking enforcement action as allowed by Tex. Gov't Code Chapters 212 or 232 or by other law available to the political subdivision. Evidence of such enforcement actions may be copies of such enforcement actions and the legal determination or resolution of those actions by the political subdivision. *The board accepts the comment and has provided basic guidelines for enforcement and compliance*.

Subsection (a)(6) requires that the board consult with the Attorney General, Secretary of State, and Texas Commission on Environmental Quality before making a determination to grant a request for temporary continuation of funding. One commenter proposed language that would provide prompt notice by the board and response by the other agencies under this requirement.

The language proposed by the commenter sets out an appropriate procedure for the agencies' actions to fulfill their responsibilities under the rule. The proposed language imposes reasonable deadlines on the agencies and does not change the scope of the rule. *The board accepts the comment and has revised subsection (a)(6) accordingly*.

In addition, the board has added a description of the contents of the request for temporary continuation of funding. This was done to facilitate submission of requests by political subdivisions and to simplify initial processing of such requests by the board.

This amendment is adopted under Texas Water Code §6.101, which provides the board with the authority to adopt rules necessary to carry out its powers and duties under the provisions of the Texas Water Code and other laws of this state, as well as under the authority of Texas Water Code §16.343, which authorizes the board to prepare and adopt model rules, §16.344, which authorizes the board to monitor the performance of a political subdivision receiving financial assistance from the EDAP, and §17.929, which provides that the board must consider whether a political subdivision has adopted and is enforcing the model rules.

§363.511. Temporary Continuation of Funding.

(a) A political subdivision may temporarily continue to receive funds under Subchapter K, Chapter 17 of the Texas Water Code, if the political subdivision submits a request for temporary continuation of funding and the board determines that:

(1) the political subdivision's initial funding application and any amendments for a designated area were reviewed and approved by the board before January 1, 2007;

(2) withholding funds would result in an undue hardship for occupants of the property to be served by unreasonably delaying the provision of adequate water or wastewater services;

(3) withholding funds would result in inefficient use of local, state, or federal funds under the program;

(4) the political subdivision has committed to taking the necessary and appropriate actions to correct any deficiencies in adoption or enforcement of the model rules pursuant to Water Code §16.343 (model rules) within the time designated by the board, but not later than the 90th day after the date the board makes the determinations under this subsection;

(5) the political subdivision has sufficient safeguards in place to prevent the proliferation of colonias; and

(6) during the 30 days after the date the board receives a request under this subsection, the board, after consulting with the Attorney General, Secretary of State, and Texas Commission on Environmental Quality, has not received an objection from any of those entities to the request for temporary continuation of funding.

(A) Within two days of receipt of the request, the board shall forward the request from the political subdivision to the Attorney General, Secretary of State, and Texas Commission on Environmental Quality.

(B) The Office of Attorney General, Secretary of State, and Texas Commission on Environmental Quality will provide their response to the board, stating either objection or no objection, within 21 days of receipt of the request from the board

(b) In applying subsection (a) of this section to applications for increased financial assistance, the board shall only consider areas that were included in the initial application, except that the board may reconsider the eligibility of areas that were the subject of a facility plan in the initial application and that may be determined to be eligible based on criteria in effect September 1, 2005.

(c) The political subdivision shall take necessary and appropriate actions to correct any deficiencies in its adoption and enforcement of the model rules within the time period required by the board, not to exceed the 90-day period described by subsection (a)(4) of this section, and provide evidence of compliance to the board. The board shall discontinue funding unless the board makes a determination based on the evidence provided that the political subdivision has demonstrated sufficient compliance to continue funding.

(d) A request for temporary continuation of funding shall be in the form and numbers prescribed by the executive administrator and, in addition to any other information that may be required by the executive administrator or the board, the applicant shall provide:

(1) a resolution from the governing body of the political subdivision that shall

(A) request that funding be continued temporarily;

(B) state the nature and purpose of the request;

(C) express the commitment of the governing body to taking the necessary actions to correct deficiencies as described in subsection (a)(4) of this section;

(D) designate an authorized representative to act on behalf of the governing body; and

(E) authorize the representative to submit the request, appear before the board on behalf of the governing body, and submit such other documentation as may be required; and

(2) a notarized affidavit from the authorized representative stating that:

(A) the decision to request temporary continuation of funding was made in a public meeting held in accordance with Government Code §§551.001 *et seq.*;

(B) the information submitted in the application is true and correct according to the best knowledge and belief of the representative; and

(C) the governing body warrants compliance with the representations made in the request in the event that the board determines temporary continuation of funding is appropriate.

(e) The board shall make its determination that the political subdivision has sufficient safeguards in place to prevent the proliferation of colonias based on such factors as:

(1) a review of the residential subdivision regulations in place;

(2) enforcement actions taken related to subdivision development;

(3) the number of colonias created since the last funding grant by the board; and

(4) other information as the board may request.

(f) Evidence of compliance by the political subdivision may include but is not limited to the consideration of such factors as:

(1) adoption of revised regulations or ordinances;

(2) approval of amended plats;

(3) documentation that minimum water or wastewater facilities are in place or that appropriate financial guarantees for improvements have been posted; or

(4) documentation of corrective actions taken by the governing board, planning commission, service provider or other authority.

(g) Except as provided by subsections (a) - (c) of this section, if the board determines that a county or city that is required to adopt and enforce the model rules is not enforcing the model rules, the board shall discontinue funding for all projects within the county or city that are funded under Subchapter K, Chapter 17.

(h) The board may not accept or grant applications for temporary funding under subsection (a) of this section after June 1, 2009.

(i) This section will expire September 1, 2009.

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 August 29, 2007.

TRD-200703998
Joe P. Reynolds
Attorney
Texas Water Development Board
Effective date: September 18, 2007
Proposal publication date: July 13, 2007
For further information, please call: (512) 936-2414

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TITLE 40. SOCIAL SERVICES AND ASSISTANCE

PART 20. TEXAS WORKFORCE COMMISSION

CHAPTER 807. CAREER SCHOOLS AND COLLEGES

The Texas Workforce Commission (Commission) adopts the following new section to Chapter 807, relating to Career Schools and Colleges, *with changes,* as published in the June 22, 2007, issue of the *Texas Register* (32 TexReg 3840):

Subchapter A, General Provisions, §807.7

The Commission adopts amendments to the following section of Chapter 807, relating to Career Schools and Colleges, *with changes,* as published in the June 22, 2007, issue of the *Texas Register* (32 TexReg 3840):

Subchapter I, Application Fees and Other Charges, §807.152

PART I. PURPOSE, BACKGROUND, AND AUTHORITY

PART II. EXPLANATION OF INDIVIDUAL PROVISIONS WITH COMMENTS AND RESPONSES

PART I. PURPOSE, BACKGROUND, AND AUTHORITY

The purpose of new §807.7, Exemptions, is to set forth a procedure for the Commission to grant exemptions and hear appeals regarding denied exemptions from the requirement for a certificate of approval. Texas Education Code, Chapter 132, provides a list of schools and courses of instruction that may be exempted from the requirements of the Texas Education Code and do not require a certificate of approval. The statute requires a school to apply to the Commission for approval of such an exemption. The new rule establishes a procedure for approving, denying, or revoking exemptions. In addition, the new rule sets forth a procedure for appealing the denial or revocation of an exemption in the same manner as the denial or revocation of a certificate of approval.

The purpose of amending §807.152 is to more closely track Texas Education Code, Chapter 132, and the flexibility it provides the Commission with regard to the range of renewal fees collected annually from career schools and colleges for purposes of program administration.

Currently, renewal fees are assessed by applying a percentage to the gross tuition and fees, excluding refunds, of a career school or college. Texas Education Code §132.201 provides that renewal fees may be set by the Commission in an amount "not to exceed 150 percent" of an amount that is determined by applying a percentage "not to exceed" 0.3%. The rule in its present form does not provide this full range of options and, as such, is more restrictive than the statute.

In adapting to circumstances, as currently, where the Commission may otherwise collect more in fees than necessary to administer Texas Education Code, Chapter 132; amending §807.152 to allow the Commission to annually establish the renewal fee percentage will provide the Commission flexibility in adapting to changing circumstances. The Commission anticipates that the result of this rule amendment, in the near term, will be a lower fee for many schools. Schools currently assessed the minimum fee will not see a reduction as the minimum does not change.

Conversely, by mirroring the provisions of Texas Education Code §132.201, the Commission will have the full range of rate-set-

ting mechanisms to address any increased need for fee income. This change ensures that the collection of renewal fees for certification of career schools and colleges is appropriately set to sufficiently cover the costs of administering the chapter.

PART II. EXPLANATION OF INDIVIDUAL PROVISIONS WITH COMMENTS AND RESPONSES

SUBCHAPTER A. GENERAL PROVISIONS

The Commission adopts the following amendments to Subchapter A:

§807.7. Exemptions

New §807.7(a) provides that a school or educational institution may apply to the Commission for an exemption under §132.002 or §132.003 of the Texas Education Code.

New §807.7(b) provides that the Commission must grant the requested exemption if the Commission determines that the school or educational institution meets the statutory requirements for an exemption under §132.002 or §132.003 of the Texas Education Code.

New §807.7(c) provides that the Commission may deny or revoke an exemption in the same manner as a denial or revocation of a certificate of approval, if the Commission determines that the school or educational institution does not meet the requirements for the exemption under §132.002 or §132.003 of the Texas Education Code.

New §807.7(d) provides that a school or educational institution may appeal the denial or revocation of an exemption in the same manner as for appealing the denial or revocation of a certificate of approval.

SUBCHAPTER I. APPLICATION FEES AND OTHER CHARGES

The Commission adopts the following amendments to Subchapter I:

§807.152. Renewal Fees

Section 807.152 is amended to annually establish the renewal fee percentage, which will provide the Commission flexibility in ensuring that the collection of renewal fees for certification of career schools and colleges is in balance with the cost of administering Chapter 132 of the Texas Education Code. In adapting to circumstances, as currently, where the Commission may otherwise collect more in fees than necessary to administer Texas Education Code, Chapter 132, enactment of this amendment is anticipated, in the near term, to allow the Commission to lower the fees currently collected and more appropriately fund the program's administration.

Comment: The commenter agreed with establishing an annual renewal fee percentage affording the Agency flexibility in setting future renewal fees-including but not limited to lowering fees for many schools. However, the commenter stated that overages in collected fees should be appropriated and spent to better administer Texas Education Code, Chapter 132. The commenter also expressed concern in processing and disseminating certificates of renewal, representative approvals, new program (and other) applications, and addressing unlicensed school violations are not timely due to the limited number of staff. The commenter asked that the Agency be tasked with collecting enough fees to increase appropriations and spending the full measure of those appropriated dollars to better administer Texas Education Code, Chapter 132, by adding additional staff to the Career Schools and Colleges program.

Response: The Commission appreciates the commenter's support of an annual renewal fee that allows the Commission flexibility to adapt to changing circumstances. By amending §807.152 to establish an annual renewal fee rate, the Commission's intent is to avoid the over collection of funds necessary to administer the Career Schools and Colleges program in order to provide appropriate services. The Commission believes the rule clearly sets forth a process that ensures the collection of renewal fees in balance with the cost of adequately administering Chapter 132. Further, the Commission recognizes the importance that staff plays in the ongoing success of the program. Staff makes every attempt at processing and disseminating all information in a timely manner. The Commission notes that the 80th Texas Legislature, Regular Session (2007) approved its Exceptional Item Appropriation request of General Revenue funding for the Fiscal Year 2008-2009 biennium, thereby increasing appropriations for two additional full-time equivalents for the Career Schools and Colleges program.

COMMENTS WERE RECEIVED FROM:

Skip Walls, Board Member and Texas Workforce Commission liaison for Career College and Schools of Texas

SUBCHAPTER A. GENERAL PROVISIONS

40 TAC §807.7

The rules are adopted under Texas Labor Code §301.0015 and §302.002(d), which provide the Texas Workforce Commission with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of Agency services and activities.

The adopted rules affect Title 4, Texas Labor Code, particularly Chapters 301 and 302, as well as Texas Education Code, Chapter 132.

§807.7. Exemptions.

(a) A school or educational institution may apply to the Commission for an exemption under §132.002 or §132.003 of the Texas Education Code.

(b) The Commission shall grant the requested exemption if the Commission determines that the school or educational institution meets the requirements for an exemption under §132.002 or §132.003 of the Texas Education Code.

(c) The Commission may deny or revoke an exemption in the same manner as a denial or revocation of a certificate of approval, if the Commission determines that the school or educational institution does not meet the requirements for the exemption under §132.002 or §132.003 of the Texas Education Code.

(d) A school or educational institution may appeal the denial or revocation of an exemption in accordance with the provisions of Subchapter D of the Texas Education Code.

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 August 28, 2007.

TRD-200703939

Reagan Miller
Deputy Division Director, Workforce Policy and Service Delivery Branch
Texas Workforce Commission
Effective date: September 17, 2007
Proposal publication date: June 22, 2007
For further information, please call: (512) 475-0829

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SUBCHAPTER I. APPLICATION FEES AND OTHER CHARGES

40 TAC §807.152

The rules are adopted under Texas Labor Code §301.0015 and §302.002(d), which provide the Texas Workforce Commission with the authority to adopt, amend, or repeal such rules as it deems necessary for the effective administration of Agency services and activities.

The adopted rules affect Title 4, Texas Labor Code, particularly Chapters 301 and 302, as well as Texas Education Code, Chapter 132.

§807.152. Renewal Fees.

(a) For small schools, if a certificate of approval is issued for more than one year, the renewal fee is $1,001, which may be paid with $501 the first year and $250 on the anniversary date of the certificate for each subsequent year.

(b) For all other schools, the renewal fee is based on the gross amount minus refunds of annual student tuition and fees. The Commission will establish the renewal fee on an annual basis, based upon the cost of administration of the chapter. The renewal fee will be set in accordance with the provisions of §132.201 of the Texas Education Code.

(c) For all schools, the Commission shall assess a penalty of 10% of the renewal fee, not less than $200 or more than $1,000, if the school fails to file a complete application for renewal at least 30 days before the expiration date of the certificate of approval.

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-200703940
Reagan Miller
Deputy Division Director, Workforce Policy and Service Delivery Branch
Texas Workforce Commission
Effective date: September 17, 2007
Proposal publication date: June 22, 2007
For further information, please call: (512) 475-0829

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TEXAS DEPARTMENT OF INSURANCE

Notification Pursuant to the Insurance Code, Chapter 5, Subchapter L

As required by the Insurance Code, Article 5.96 and 5.97, the ***Texas Register*** publishes notice of proposed actions by the Texas Department of Insurance. Notice of action proposed under Article 5.96 must be published in the ***Texas Register*** not later than the 30th day before the proposal is adopted. Notice of action proposed under Article 5.97 must be published in the ***Texas Register*** not later than the 10th day before the proposal is adopted. The Administrative Procedure Act, Government Code, Chapters 2001 and 2002, does not apply to department action under Articles 5.96 and 5.97.

The complete text of the proposal summarized here may be examined in the offices of the Texas Department of Insurance, 333 Guadalupe Street, Austin, Texas 78701.

This notification is made pursuant to the Insurance Code, Article 5.96, which exempts it from the requirements of the Administrative Procedure Act.

Texas Department of Insurance

Proposed Action on Rules

EXEMPT FILING NOTIFICATION PURSUANT TO THE INSURANCE CODE CHAPTER 5, SUBCHAPTER L, ARTICLE 5.96

The Commissioner of Insurance (Commissioner) will hold a public hearing under Docket No. 2671 on October 3, 2007, at 9:30 a.m., in Room 100 of the William P. Hobby Building, 333 Guadalupe Street in Austin, Texas to consider a petition by the staff of the Texas Department of Insurance (Department) proposing the adoption of revised Texas Workers' Compensation Classification Relativities (classification relativities) to replace those adopted pursuant to Commissioner's Order No. 06-1309, dated December 15, 2006; and the adoption of a revised table to amend the Texas Basic Manual of Rules, Classification, and Experience Rating Plan for Workers' Compensation and Employers' Liability Insurance (Basic Manual) concerning the Expected Loss Rates and Discount Ratios used in experience rating. Staff's petition (Reference No. W-0907-10-I) was filed on September 4, 2007.

Staff requests that the proposed revised classification relativities be available for adoption by insurers immediately, but that their use be mandatory for all policies with an effective date on or after January 1, 2008, unless the insurer makes an independent filing to justify insurer-specific classification relativities. Staff further requests that the revised table amending the Basic Manual be made effective for workers' compensation experience modifiers with an effective date on or after January 1, 2008.

Texas Insurance Code §2053.051 requires the Department to determine hazards by class and establish classification relativities applicable to the payroll in each class for workers' compensation insurance. Section 2053.052 requires the Commissioner to adopt a uniform experience rating plan for workers' compensation insurance. Sections 2053.051 and 2053.052 further provide that the classification system and experience rating plans be revised at least once every five years.

The classification relativities currently in effect are based on experience data reflecting workers' compensation experience from policies with effective dates in 1999 through 2003. The proposed classification relativities are based on the analysis of experience data from policies with effective dates in 2000 through 2004. Staff's proposed classification relativities reflect changes in experience that occur over time.

Current classification relativities are at an average level of 65% of the overall average level of the 1994 classification relativities. This 65% level was adopted pursuant to Commissioner's Order No. 04-1001, dated October 14, 2004, to better reflect improvements in experience that had occurred with the passage of time.

Recent data and projections show that Texas loss experience has continued to improve. Therefore, staff proposes that each of the revised classification relativities be multiplied by a factor of 60/65, to bring the relativities to 60% of the overall average of the 1994 classification relativities.

Staff recommends capping changes in the proposed classification relativities to +25% and -25% of the current classification relativities prior to the adjustment to reduce the classification relativities to 60% of the 1994 classification relativities. After adjustment for the latter change, the proposed classification relativities will range from +15.4% to -30.8% of the current classification relativities.

Modifications to the classification relativities require concurrent changes in the expected loss rates and discount ratios, which are contained in Table II of the Basic Manual. The proposed expected loss rates are based on the anticipated level of the losses that were used to experience rate the average policy effective in 2008. Such a policy would be effective on July 1, 2008, and would reflect the proposed classification relativities. Staff also proposes to cap changes in the expected loss rates to +25% and -25% from the current expected loss rates. Staff also proposes to revise the discount ratios in Table II to reflect the ratios that will exist for losses used to experience rate policies effective in 2008. The changes in the discount ratios are not subject to capping.

Copies of the full text of the staff petition and a schedule of the proposed revised classification relativities and a table of the proposed expected loss rates and discount ratios are available for review in the Office of the Chief Clerk of the Texas Department of Insurance, 333 Guadalupe Street, Austin, Texas 78714-9104. For further information or to request copies of the petition and proposed revised schedule and table, please contact Sylvia Gutierrez at ChiefClerk@tdi.state.tx.us, (512) 463-6327 (Reference No. W-0907-10-I).

Comments on the proposed changes may be submitted in writing by 5:00 p.m. on October 15, 2007, to Gene Jarmon, General Counsel and Chief Clerk, P.O. Box 149104, MC 113-2A, Austin, Texas 78714-9104. An additional copy of the comment should be simultaneously submitted to J'ne Byckovski, Chief Actuary, Property and Casualty Program, P.O. Box 149104, MC 105-5F, Austin, Texas 78714-9104. Interested persons may also submit oral and/or written comments at the hearing.

This notification is made pursuant to the Texas Insurance Code, Article 5.96, which exempts action taken under this article from the require-

ments of the Administrative Procedure Act (Government Code, Title 10, Ch. 2001).

TRD-200704078
Gene C. Jarmon
General Counsel and Chief Clerk
Texas Department of Insurance
Filed: September 4, 2007

♦ ♦ ♦

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.

Proposed Rule Reviews

Texas Medical Board

Title 22, Part 9

The Texas Medical Board proposes to review Chapter 162, §162.1 and §162.2, concerning Supervision of Medical School Students, pursuant to the Texas Government Code, §2001.039.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously proposes an amendment to §162.1.

The agency's reason for adopting the rules contained in this chapter continues to exist.

Comments on the proposed review may be submitted to Sally Durocher, P.O. Box 2018, Austin, Texas 78768-2018.

TRD-200704027
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Filed: August 31, 2007

♦ ♦ ♦

The Texas Medical Board proposes to review Chapter 164, §§164.1 - 164.5, concerning Physician Advertising, pursuant to the Texas Government Code, §2001.039.

The agency's reason for adopting the rules contained in this chapter continues to exist.

Comments on the proposed review may be submitted to Sally Durocher, P.O. Box 2018, Austin, Texas 78768-2018.

TRD-200704028
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Filed: August 31, 2007

♦ ♦ ♦

The Texas Medical Board proposes to review Chapter 173, §§173.1 - 173.5 and 173.7, concerning Physician Profiles, pursuant to the Texas Government Code, §2001.039.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously proposes amendments to §§173.1, 173.2 and 173.5.

The agency's reason for adopting the rules contained in this chapter continues to exist.

Comments on the proposed review may be submitted to Sally Durocher, P.O. Box 2018, Austin, Texas 78768-2018.

TRD-200704029
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Filed: August 31, 2007

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The Texas Medical Board proposes to review Chapter 196, §§196.1 - 196.5, concerning Voluntary Relinquishment or Surrender of a Medical License, pursuant to the Texas Government Code, §2001.039.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously proposes amendments to §196.2 and §196.3.

The agency's reason for adopting the rules contained in this chapter continues to exist.

Comments on the proposed review may be submitted to Sally Durocher, P.O. Box 2018, Austin, Texas 78768-2018.

TRD-200704030
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Filed: August 31, 2007

♦ ♦ ♦

The Texas Medical Board proposes to review Chapter 198, §§198.1 - 198.6, concerning Unlicensed Practice, pursuant to the Texas Government Code, §2001.039.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously proposes amendments to §198.2 and §198.3.

The agency's reason for adopting the rules contained in this chapter continues to exist.

Comments on the proposed review may be submitted to Sally Durocher, P.O. Box 2018, Austin, Texas 78768-2018.

TRD-200704031
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Filed: August 31, 2007

♦ ♦ ♦

The Texas Medical Board proposes to review Chapter 199, §§199.1 - 199.5, concerning Public Information, pursuant to the Texas Government Code, §2001.039.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously proposes amendments to §199.1 and §§199.3 - 199.5.

The agency's reason for adopting the rules contained in this chapter continues to exist.

Comments on the proposed review may be submitted to Sally Durocher, P.O. Box 2018, Austin, Texas 78768-2018.

TRD-200704032
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Filed: August 31, 2007

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Adopted Rule Reviews

Texas Education Agency

Title 19, Part 2

The Texas Education Agency (TEA) adopts the review of 19 TAC Chapter 53, Regional Education Service Centers, Subchapter AA, Commissioner's Rules, pursuant to the Texas Government Code, §2001.039. The TEA proposed the review of 19 TAC Chapter 53, Subchapter AA, in the May 4, 2007, issue of the *Texas Register* (32 TexReg 2483).

The TEA finds that the reasons for adopting 19 TAC Chapter 53, Subchapter AA, continue to exist.

Comment. The Texas Classroom Teachers Association (TCTA) commented that the rule prohibiting people engaged in public education from serving on education service center (ESC) boards of directors should be changed. The TCTA recommended that, with teachers as the focus of much of the work conducted by ESCs, teachers should be allowed on the boards in order to convey the best strategy for improving services to teachers. The TCTA proposed an election process whereby one of the regional teachers of the year would be selected to serve on the ESC board of directors on a basis determined by the TEA. The TCTA also stated that although legislation requiring this change (Senate Bill (SB) 1644) was not passed by the 80th Texas Legislature, 2007, there was substantial support for such a change.

Agency Response. The agency disagrees. The TCTA noted that one of the reasons it suggested changing the provision that no one engaged in education should be considered for an ESC board of directors is that the prohibition is too broad. The TCTA suggested that a non-voting regional teacher of the year would bring a new perspective to the board because much of the work of the education service centers is directed at the provision of professional development for teachers. While this may be the case, the concern expressed in the prohibition is still valid. The prohibition is directed at the possibility that a board member engaged in education could influence the work of the centers in directing business to a school district or institution of higher education or corporation involved in the educational process. By adding a teacher to the board even as a non-voting member, the interests of that group increase. If a teacher is added, district administrators or faculty members of institutions of higher education may also request a seat on the board. Regional education service centers should function on a neutral basis. The way to help guarantee that neutrality is to keep the membership of the ESC boards of directors free of stakeholder influence. The current structure for ESC boards of directors is established in statute.

Finally, the TCTA stated that the Texas Senate, during the 80th Texas Legislature, 2007, passed SB 1644 and sent it to the Texas House of Representatives. The bill would have accomplished the restructuring of the ESC boards of directors. The TCTA suggested that the widespread support generated by the bill demonstrated the value in including teachers on ESC boards. However, the House did not debate or vote on the legislation, and it is unknown whether it would have had the support of a majority of the members of the House.

No changes are being proposed as a result of the review.

This concludes the review of 19 TAC Chapter 53.

TRD-200704065
Cristina De La Fuente-Valadez
Director, Policy Division
Texas Education Agency
Filed: September 4, 2007

♦ ♦ ♦

Texas Medical Board

Title 22, Part 9

The Texas Medical Board adopts the review of Chapter 176, §§176.1 - 176.9, concerning Health Care Liability Lawsuits and Settlements, pursuant to the Texas Government Code, §2001.039.

The proposed review was published in the June 29, 2007, issue of the *Texas Register* (32 TexReg 4016).

No comments were received regarding adoption of the review.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously adopts amendments to §§176.1, 176.2, 176.4, 176.6, 176.8 and 176.9.

The agency's reason for adopting the rules contained in this chapter continues to exist.

This concludes the review of Chapter 176, Health Care Liability Lawsuits and Settlements.

TRD-200704033
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Filed: August 31, 2007

♦ ♦ ♦

The Texas Medical Board adopts the review of Chapter 181, §§181.1 - 181.7, concerning Contact Lens Prescriptions, pursuant to the Texas Government Code, §2001.039.

The proposed review was published in the June 29, 2007, issue of the *Texas Register* (32 TexReg 4016).

No comments were received regarding adoption of the review.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously adopts amendments to §§181.2, 181.3 and 181.6.

The agency's reason for adopting the rules contained in this chapter continues to exist.

This concludes the review of Chapter 181, Contact Lens Prescriptions.

TRD-200704034

Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Filed: August 31, 2007

♦ ♦ ♦

The Texas Medical Board adopts the review of Chapter 191, §§191.1 - 191.5, concerning District Review Committees, pursuant to the Texas Government Code, §2001.039.

The proposed review was published in the June 29, 2007, issue of the *Texas Register* (32 TexReg 4016).

No comments were received regarding adoption of the review.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously adopts amendments to §191.4.

The agency's reason for adopting the rules contained in this chapter continues to exist.

This concludes the review of Chapter 191, District Review Committees.

TRD-200704035
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Filed: August 31, 2007

♦ ♦ ♦

The Texas Medical Board adopts the review of Chapter 194, §§194.1 - 194.9 and 194.11, concerning Non-Certified Radiologic Technicians, pursuant to the Texas Government Code, §2001.039.

The proposed review was published in the June 29, 2007, issue of the *Texas Register* (32 TexReg 4016).

No comments were received regarding adoption of the review.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously adopts amendments to §§194.2 - 194.6.

The agency's reason for adopting the rules contained in this chapter continues to exist.

This concludes the review of Chapter 194, Non-Certified Radiologic Technicians.

TRD-200704069
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Filed: September 4, 2007

♦ ♦ ♦

The Texas Medical Board adopts the review of Chapter 197, §§197.1 - 197.6, concerning Emergency Medical Service, pursuant to the Texas Government Code, §2001.039.

The proposed review was published in the June 29, 2007, issue of the *Texas Register* (32 TexReg 4016).

No comments were received regarding adoption of the review.

Elsewhere in this issue of the *Texas Register*, the Texas Medical Board contemporaneously adopts amendments to §§197.1 - 197.4.

The agency's reason for adopting the rules contained in this chapter continues to exist.

This concludes the review of Chapter 197, Emergency Medical Service.

TRD-200704036
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Filed: August 31, 2007

♦ ♦ ♦

The Texas Medical Board adopts the review of Chapter 200, §§200.1 - 200.3, concerning Standards for Physicians Practicing Complementary and Alternative Medicine, pursuant to the Texas Government Code, §2001.039.

The proposed review was published in the June 29, 2007, issue of the *Texas Register* (32 TexReg 4016).

No comments were received regarding adoption of the review.

The agency's reason for adopting the rules contained in this chapter continues to exist.

This concludes the review of Chapter 200, Standards for Physicians Practicing Complementary and Alternative Medicine.

TRD-200704037
Donald W. Patrick, MD, JD
Executive Director
Texas Medical Board
Filed: August 31, 2007

♦ ♦ ♦

Texas State Board of Pharmacy

Title 22, Part 15

The Texas State Board of Pharmacy adopts the review of Chapter 291, Subchapter F (§§291.101 - 291.105), concerning Non-Resident Pharmacy (Class E), pursuant to the Texas Government Code §2001.039, regarding Agency Review of Existing Rules. The proposed review was published in the May 25, 2007, issue of the *Texas Register* (32 TexReg 2883).

No comments were received regarding the proposed rule review.

The agency finds the reason for adopting the rules continues to exist; therefore, the agency readopts Chapter 291, Subchapter F.

TRD-200703996
Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Filed: August 29, 2007

♦ ♦ ♦

The Texas State Board of Pharmacy adopts the review of Chapter 295 (§§295.1 - 295.9, 295.11, 295.13, 295.15), concerning Pharmacists, pursuant to the Texas Government Code §2001.039, regarding Agency Review of Existing Rules. The proposed review was published in the May 25, 2007, issue of the *Texas Register* (32 TexReg 2883).

No comments were received regarding the proposed rule review.

The agency finds the reason for adopting the rules continues to exist; therefore, the agency readopts Chapter 295.

TRD-200703997

Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
Filed: August 29, 2007

♦ ♦ ♦

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: 25 TAC §289.257(i)(5)(E)(i)

$$CSI = 10\left[\frac{grams^{235}U}{X} + \frac{grams^{233}U}{Y} + \frac{gramsPu}{Z}\right]$$

Figure: 25 TAC §289.257(i)(5)(E)(iii)

Table 257-1 Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per §289.257(i)(5)(E)		
Fissile Material	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O. (grams)	Fissile material mass mixed with moderating substances having an average hydrogen density greater than H_2O [a]. (grams)
^{235}U (X)	60	38
^{233}U (Y)	43	27
^{239}PU or ^{241}PU (Z)	37	24

[a]When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15% of the moderating substance has an average hydrogen density greater than H_2O.

Table 257-2 Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per §289.257(i)(5)(E)	
Uranium enrichment in weight percent of ^{235}U not exceeding	Fissile material mass of ^{235}U (X). (grams)
24	60
20	63
15	67
11	72
10	76
9.5	78
9	81
8.5	82
8	85
7.5	88
7	90
6.5	93
6	97
5.5	102
5	108
4.5	114
4	120
3.5	132
3	150
2.5	180
2	246
1.5	408
1.35	480
1	1,020
0.92	1,800

Figure: 25 TAC §289.257(i)(6)(E)(i)

$$CSI = 10\left[\frac{grams^{232}Pu + grams^{241}Pu}{24}\right]; \text{ and}$$

Figure: 25 TAC §289.257(aa)(4)(A)

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide I, and $A_1(i)$ is the A_1 value for radionuclide I.

Figure: 25 TAC §289.257(aa)(4)(B)

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide I and $A_2(i)$ is the A_2 value for radionuclide I.

Figure: 25 TAC §289.257(aa)(4)(C)

$$A_1 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity of nuclide I in the mixture and $A_1(i)$ is the appropriate A_1 value for nuclide I.

Figure: 25 TAC §289.257(aa)(4)(D)

$$A_2 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity of nuclide I in the mixture and $A_2(i)$ is the appropriate A_2 value for nuclide I.

Figure: 25 TAC §289.257(aa)(4)(E)

$$\text{Exempt activity concentration for mixture} = \frac{1}{\sum \frac{f(i)}{[A](i)}}$$

where f(i) is the fraction of activity concentration of radionuclide I in the mixture, and [A] is the activity concentration for exempt material containing radionuclide I.

Figure: 25 TAC §289.257(aa)(4)(F)

$$\text{Exempt activity concentration for mixture} = \frac{1}{\sum \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide I in the mixture, and A is the activity limit for exempt consignments for radionuclide I.

Figure: 25 TAC §289.257(aa)(6)
Table 257-3

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Ac-225 (a)	Actinium (89)	$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.1X10^{3}$	$5.8X10^{4}$
Ac-227 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-5}$	$2.4X10^{-3}$	2.7	$7.2X10^{1}$
Ac-228		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.4X10^{4}$	$2.2X10^{6}$
Ag-105	Silver (47)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Ag-108m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.7X10^{-1}$	$2.6X10^{1}$
Ag-110m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.8X10^{2}$	$4.7X10^{3}$
Ag-111		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Al-26	Aluminum (13)	$1.0X10^{-1}$	2.7	$1.0X10^{-1}$	2.7	$7.0X10^{-4}$	$1.9X10^{-2}$
Am-241	Americium (95)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.3X10^{-1}$	3.4
Am-242m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.6X10^{-1}$	$1.0X10^{1}$
Am-243 (a)		5.0	$1.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.4X10^{-3}$	$2.0X10^{-1}$
Ar-37	Argon (18)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.7X10^{3}$	$9.9X10^{4}$
Ar-39		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	1.3	$3.4X10^{1}$
Ar-41		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.5X10^{6}$	$4.2X10^{7}$
As-72	Arsenic (33)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$6.2X10^{4}$	$1.7X10^{6}$
As-73		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.2X10^{2}$	$2.2X10^{4}$
As-74		1.0	$2.7X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$3.7X10^{3}$	$9.9X10^{4}$
As-76		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.8X10^{4}$	$1.6X10^{6}$
As-77		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.9X10^{4}$	$1.0X10^{6}$
At-211 (a)	Astatine (85)	$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.6X10^{4}$	$2.1X10^{6}$
Au-193	Gold (79)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$3.4X10^{4}$	$9.2X10^{5}$
Au-194		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{4}$	$4.1X10^{5}$
Au-195		$1.0X10^{1}$	$2.7X10^{2}$	6.0	$1.6X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Au-198		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.0X10^{3}$	$2.4X10^{5}$
Au-199		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{3}$	$2.1X10^{5}$
Ba-131 (a)	Barium (56)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Ba-133		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	9.4	$2.6X10^{2}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Ba-133m		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{4}$	$6.1X10^{5}$
Ba-140 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{-1}$	8.1	$2.7X10^{3}$	$7.3X10^{4}$
Be-7	Beryllium (4)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.3X10^{4}$	$3.5X10^{5}$
Be-10		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$8.3X10^{-4}$	$2.2X10^{-2}$
Bi-205	Bismuth (83)	$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{3}$	$4.2X10^{4}$
Bi-206		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.8X10^{3}$	$1.0X10^{5}$
Bi-207		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	1.9	$5.2X10^{1}$
Bi-210		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
Bi-210m (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.1X10^{-5}$	$5.7X10^{-4}$
Bi-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{5}$	$1.5X10^{7}$
Bk-247	Berkelium (97)	8.0	$2.2X10^{2}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$3.8X10^{-2}$	1.0
Bk-249 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{-1}$	8.1	$6.1X10^{1}$	$1.6X10^{3}$
Br-76	Bromine (35)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$9.4X10^{4}$	$2.5X10^{6}$
Br-77		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$2.6X10^{4}$	$7.1X10^{5}$
Br-82		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{4}$	$1.1X10^{6}$
C-11	Carbon (6)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.1X10^{7}$	$8.4X10^{8}$
C-14		$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{-1}$	4.5
Ca-41	Calcium (20)	Unlimited	Unlimited	Unlimited	Unlimited	$3.1X10^{-3}$	$8.5X10^{-2}$
Ca-45		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Ca-47 (a)		3.0	$8.1X10^{1}$	$3.0X10^{-1}$	8.1	$2.3X10^{4}$	$6.1X10^{5}$
Cd-109	Cadmium (48)	$3.0X10^{1}$	$8.1X10^{2}$	2.0	$5.4X10^{1}$	$9.6X10^{1}$	$2.6X10^{3}$
Cd-113m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	8.3	$2.2X10^{2}$
Cd-115 (a)		3.0	$8.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.9X10^{4}$	$5.1X10^{5}$
Cd-115m		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.4X10^{2}$	$2.5X10^{4}$
Ce-139	Cerium (58)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$2.5X10^{2}$	$6.8X10^{3}$
Ce-141		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.8X10^{4}$
Ce-143		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.6X10^{5}$
Ce-144 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.2X10^{3}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Cf-248	Californium (98)	$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$5.8X10^{1}$	$1.6X10^{3}$
Cf-249		3.0	$8.1X10^{1}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$1.5X10^{-1}$	4.1
Cf-250		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	4.0	$1.1X10^{2}$
Cf-251		7.0	$1.9X10^{2}$	$7.0X10^{-4}$	$1.9X10^{-2}$	$5.9X10^{-2}$	1.6
Cf-252 (h)		$5.0X10^{-2}$	1.4	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.4X10^{2}$
Cf-253 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-2}$	1.1	$1.1X10^{3}$	$2.9X10^{4}$
Cf-254		$1.0X10^{-3}$	$2.7X10^{-2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.1X10^{2}$	$8.5X10^{3}$
Cl-36	Chlorine (17)	$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{-3}$	$3.3X10^{-2}$
Cl-38		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$4.9X10^{6}$	$1.3X10^{8}$
Cm-240	Curium (96)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$7.5X10^{2}$	$2.0X10^{4}$
Cm-241		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$6.1X10^{2}$	$1.7X10^{4}$
Cm-242		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$1.2X10^{2}$	$3.3X10^{3}$
Cm-243		9.0	$2.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.9X10^{-3}$	$5.2X10^{1}$
Cm-244		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	3.0	$8.1X10^{1}$
Cm-245		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$6.4X10^{-3}$	$1.7X10^{-1}$
Cm-246		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$1.1X10^{-2}$	$3.1X10^{-1}$
Cm-247 (a)		3.0	$8.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.4X10^{-6}$	$9.3X10^{-5}$
Cm-248		$2.0X10^{-2}$	$5.4X10^{-1}$	$3.0X10^{-4}$	$8.1X10^{-3}$	$1.6X10^{-4}$	$4.2X10^{-3}$
Co-55	Cobalt (27)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Co-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{3}$	$3.0X10^{4}$
Co-57		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$3.1X10^{2}$	$8.4X10^{3}$
Co-58		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Co-58m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.2X10^{5}$	$5.9X10^{6}$
Co-60		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.2X10^{1}$	$1.1X10^{3}$
Cr-51	Chromium (24)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.4X10^{3}$	$9.2X10^{4}$
Cs-129	Cesium (55)	4.0	$1.1X10^{2}$	4.0	$1.1X10^{2}$	$2.8X10^{4}$	$7.6X10^{5}$
Cs-131		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.8X10^{3}$	$1.0X10^{5}$
Cs-132		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.7X10^{3}$	$1.5X10^{5}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Cs-134		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.8X10^{1}$	$1.3X10^{3}$
Cs-134m		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.0X10^{6}$
Cs-135		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$4.3X10^{-5}$	$1.2X10^{-3}$
Cs-136		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.7X10^{3}$	$7.3X10^{4}$
Cs-137 (a)		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	3.2	$8.7X10^{1}$
Cu-64	Copper (29)	6.0	$1.6X10^{2}$	1.0	$2.7X10^{1}$	$1.4X10^{5}$	$3.9X10^{6}$
Cu-67		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.8X10^{4}$	$7.6X10^{5}$
Dy-159	Dysprosium (66)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$2.1X10^{2}$	$5.7X10^{3}$
Dy-165		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Dy-166 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$3.0X10^{-1}$	8.1	$8.6X10^{3}$	$2.3X10^{5}$
Er-169	Erbium (68)	$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$3.1X10^{3}$	$8.3X10^{4}$
Er-171		$8.0X10^{-1}$	$2.2X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.0X10^{4}$	$2.4X10^{6}$
Eu-147	Europium (63)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.4X10^{3}$	$3.7X10^{4}$
Eu-148		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.0X10^{2}$	$1.6X10^{4}$
Eu-149		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$3.5X10^{2}$	$9.4X10^{3}$
Eu-150 (short lived)		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-150 (long lived)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-152		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	6.5	$1.8X10^{2}$
Eu-152m		$8.0X10^{-1}$	$2.2X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$8.2X10^{4}$	$2.2X10^{6}$
Eu-154		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	9.8	$2.6X10^{2}$
Eu-155		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$1.8X10^{1}$	$4.9X10^{2}$
Eu-156		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{3}$	$5.5X10^{4}$
F-18	Fluorine (9)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.5X10^{6}$	$9.5X10^{7}$
Fe-52 (a)	Iron (26)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.7X10^{5}$	$7.3X10^{6}$
Fe-55		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.8X10^{1}$	$2.4X10^{3}$
Fe-59		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$1.8X10^{3}$	$5.0X10^{4}$
Fe-60 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-1}$	5.4	$7.4X10^{-4}$	$2.0X10^{-2}$
Ga-67	Gallium (31)	7.0	$1.9X10^{2}$	3.0	$8.1X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Ga-68		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.5X10^{6}$	$4.1X10^{7}$
Ga-72		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Gd-146 (a)	Gadolinium (64)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Gd-148		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	1.2	$3.2X10^{1}$
Gd-153		$1.0X10^{1}$	$2.7X10^{2}$	9.0	$2.4X10^{2}$	$1.3X10^{2}$	$3.5X10^{3}$
Gd-159		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.9X10^{4}$	$1.1X10^{6}$
Ge-68 (a)	Germanium (32)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.6X10^{2}$	$7.1X10^{3}$
Ge-71		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.8X10^{3}$	$1.6X10^{5}$
Ge-77		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Hf-172 (a)	Hafnium (72)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Hf-175		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$3.9X10^{2}$	$1.1X10^{4}$
Hf-181		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.3X10^{2}$	$1.7X10^{4}$
Hf-182		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-6}$	$2.2X10^{-4}$
Hg-194 (a)	Mercury (80)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.3X10^{-1}$	3.5
Hg-195m (a)		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Hg-197		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.2X10^{3}$	$2.5X10^{5}$
Hg-197m		$1.0X10^{1}$	$2.7X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.5X10^{4}$	$6.7X10^{5}$
Hg-203		5.0	$1.4X10^{2}$	1.0	$2.7X10^{1}$	$5.1X10^{2}$	$1.4X10^{4}$
Ho-166	Holmium (67)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
Ho-166m		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.6X10^{-2}$	1.8
I-123	Iodine (53)	6.0	$1.6X10^{2}$	3.0	$8.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$
I-124		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$9.3X10^{3}$	$2.5X10^{5}$
I-125		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$6.4X10^{2}$	$1.7X10^{4}$
I-126		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{3}$	$8.0X10^{4}$
I-129		Unlimited	Unlimited	Unlimited	Unlimited	$6.5X10^{-6}$	$1.8X10^{-4}$
I-131		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
I-132		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.8X10^{5}$	$1.0X10^{7}$
I-133		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{4}$	$1.1X10^{6}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
I-134		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$9.9X10^{5}$	$2.7X10^{7}$
I-135 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.3X10^{5}$	$3.5X10^{6}$
In-111	Indium (49)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.5X10^{4}$	$4.2X10^{5}$
In-113m		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$6.2X10^{5}$	$1.7X10^{7}$
In-114m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.6X10^{2}$	$2.3X10^{4}$
In-115m		7.0	$1.9X10^{2}$	1.0	$2.7X10^{1}$	$2.2X10^{5}$	$6.1X10^{6}$
Ir-189 (a)	Iridium (77)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.9X10^{3}$	$5.2X10^{4}$
Ir-190		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.3X10^{3}$	$6.2X10^{4}$
Ir-192 (c)		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.4X10^{2}$	$9.2X10^{3}$
Ir-194		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.1X10^{4}$	$8.4X10^{5}$
K-40	Potassium (19)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.4X10^{-7}$	$6.4X10^{-6}$
K-42		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.2X10^{5}$	$6.0X10^{6}$
K-43		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Kr-81	Krypton (36)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$7.8X10^{-4}$	$2.1X10^{-2}$
Kr-85		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.5X10^{1}$	$3.9X10^{2}$
Kr-85m		8.0	$2.2X10^{2}$	3.0	$8.1X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Kr-87		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.0X10^{6}$	$2.8X10^{7}$
La-137	Lanthanum (57)	$3.0X10^{1}$	$8.1X10^{2}$	6.0	$1.6X10^{2}$	$1.6X10^{-3}$	$4.4X10^{-2}$
La-140		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.1X10^{4}$	$5.6X10^{5}$
Lu-172	Lutetium (71)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{3}$	$1.1X10^{5}$
Lu-173		8.0	$2.2X10^{2}$	8.0	$2.2X10^{2}$	$5.6X10^{1}$	$1.5X10^{3}$
Lu-174		9.0	$2.4X10^{2}$	9.0	$2.4X10^{2}$	$2.3X10^{1}$	$6.2X10^{2}$
Lu-174m		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$2.0X10^{2}$	$5.3X10^{3}$
Lu-177		$3.0X10^{1}$	$8.1X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.1X10^{3}$	$1.1X10^{5}$
Mg-28 (a)	Magnesium (12)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{5}$	$5.4X10^{6}$
Mn-52	Manganese (25)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.6X10^{4}$	$4.4X10^{5}$
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	$6.8X10^{-5}$	$1.8X10^{-3}$
Mn-54		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{2}$	$7.7X10^{3}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Mn-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.0X10^{5}$	$2.2X10^{7}$
Mo-93	Molybdenum (42)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.1X10^{-2}$	1.1
Mo-99 (a) (i)		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{4}$	$4.8X10^{5}$
N-13	Nitrogen (7)	$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{7}$	$1.5X10^{9}$
Na-22	Sodium (11)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.3X10^{3}$
Na-24		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.2X10^{5}$	$8.7X10^{6}$
Nb-93m	Niobium (41)	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	8.8	$2.4X10^{2}$
Nb-94		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.9X10^{-3}$	$1.9X10^{-1}$
Nb-95		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{3}$	$3.9X10^{4}$
Nb-97		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.9X10^{5}$	$2.7X10^{7}$
Nd-147	Neodymium (60)	6.0	$1.6X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Nd-149		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{5}$	$1.2X10^{7}$
Ni-59	Nickel (28)	Unlimited	Unlimited	Unlimited	Unlimited	$3.0X10^{-3}$	$8.0X10^{-2}$
Ni-63		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	2.1	$5.7X10^{1}$
Ni-65		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{5}$	$1.9X10^{7}$
Np-235	Neptunium (93)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.2X10^{1}$	$1.4X10^{3}$
Np-236 (short-lived)		$2.0X10^{1}$	$5.4X10^{2}$	2.0	$5.4X10^{1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-236 (long-lived)		$9.0X10^{0}$	$2.4X10^{2}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$2.6X10^{-5}$	$7.1X10^{-4}$
Np-239		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$8.6X10^{3}$	$2.3X10^{5}$
Os-185	Osmium (76)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.8X10^{2}$	$7.5X10^{3}$
Os-191		$1.0X10^{1}$	$2.7X10^{2}$	2.0	$5.4X10^{1}$	$1.6X10^{3}$	$4.4X10^{4}$
Os-191m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.6X10^{4}$	$1.3X10^{6}$
Os-193		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{4}$	$5.3X10^{5}$
Os-194 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{1}$	$3.1X10^{2}$
P-32	Phosphorus (15)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{4}$	$2.9X10^{5}$
P-33		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pa-230 (a)	Protactinium (91)	2.0	$5.4X10^{1}$	$7.0X10^{-2}$	1.9	$1.2X10^{3}$	$3.3X10^{4}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Pa-231		4.0	$1.1X10^{2}$	$4.0X10^{-4}$	$1.1X10^{-2}$	$1.7X10^{-3}$	$4.7X10^{-2}$
Pa-233		5.0	$1.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.7X10^{2}$	$2.1X10^{4}$
Pb-201	Lead (82)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.2X10^{4}$	$1.7X10^{6}$
Pb-202		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.2X10^{-4}$	$3.4X10^{-3}$
Pb-203		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	$4.5X10^{-6}$	$1.2X10^{-4}$
Pb-210 (a)		1.0	$2.7X10^{1}$	$5.0X10^{-2}$	1.4	2.8	$7.6X10^{1}$
Pb-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{-1}$	5.4	$5.1X10^{4}$	$1.4X10^{6}$
Pd-103 (a)	Palladium (46)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.8X10^{3}$	$7.5X10^{4}$
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	$1.9X10^{-5}$	$5.1X10^{-4}$
Pd-109		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.9X10^{4}$	$2.1X10^{6}$
Pm-143	Promethium (61)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.3X10^{2}$	$3.4X10^{3}$
Pm-144		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.2X10^{1}$	$2.5X10^{3}$
Pm-145		$3.0X10^{1}$	$8.1X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	5.2	$1.4X10^{2}$
Pm-147		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$3.4X10^{1}$	$9.3X10^{2}$
Pm-148m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Pm-149		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Pm-151		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.7X10^{4}$	$7.3X10^{5}$
Po-210	Polonium (84)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.7X10^{2}$	$4.5X10^{3}$
Pr-142	Praseodymium (59)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.3X10^{4}$	$1.2X10^{6}$
Pr-143		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{3}$	$6.7X10^{4}$
Pt-188 (a)	Platinum (78)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$2.5X10^{3}$	$6.8X10^{4}$
Pt-191		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$8.7X10^{3}$	$2.4X10^{5}$
Pt-193		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	1.4	$3.7X10^{1}$
Pt-193m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pt-195m		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.2X10^{3}$	$1.7X10^{5}$
Pt-197		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.2X10^{4}$	$8.7X10^{5}$
Pt-197m		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.7X10^{5}$	$1.0X10^{7}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Pu-236	Plutonium (94)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.3X10^{2}$
Pu-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.5X10^{2}$	$1.2X10^{4}$
Pu-238		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.3X10^{-1}$	$1.7X10^{1}$
Pu-239		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$2.3X10^{-3}$	$6.2X10^{-2}$
Pu-240		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.4X10^{-3}$	$2.3X10^{-1}$
Pu-241 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-2}$	1.6	3.8	$1.0X10^{2}$
Pu-242		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.5X10^{-4}$	$3.9X10^{-3}$
Pu-244 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.7X10^{-7}$	$1.8X10^{-5}$
Ra-223 (a)	Radium (88)	$4.0X10^{-1}$	$1.1X10^{1}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$1.9X10^{3}$	$5.1X10^{4}$
Ra-224 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$5.9X10^{3}$	$1.6X10^{5}$
Ra-225 (a)		$2.0X10^{-1}$	5.4	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.5X10^{3}$	$3.9X10^{4}$
Ra-226 (a)		$2.0X10^{-1}$	5.4	$3.0X10^{-3}$	$8.1X10^{-2}$	$3.7X10^{-2}$	1.0
Ra-228 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.0X10^{1}$	$2.7X10^{2}$
Rb-81	Rubidium (37)	2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{5}$	$8.4X10^{6}$
Rb-83 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$6.8X10^{2}$	$1.8X10^{4}$
Rb-84		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.8X10^{3}$	$4.7X10^{4}$
Rb-86		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	$3.2X10^{-9}$	$8.6X10^{-8}$
Rb(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$6.7X10^{6}$	$1.8X10^{8}$
Re-184	Rhenium (75)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Re-184m		3.0	$8.1X10^{1}$	1.0	$2.7X10^{1}$	$1.6X10^{2}$	$4.3X10^{3}$
Re-186		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.9X10^{3}$	$1.9X10^{5}$
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	$1.4X10^{-9}$	$3.8X10^{-8}$
Re-188		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.6X10^{4}$	$9.8X10^{5}$
Re-189 (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.8X10^{5}$
Re(nat)		Unlimited	Unlimited	Unlimited	Unlimited	0.0	$2.4X10^{-8}$
Rh-99	Rhodium (45)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Rh-101		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$

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						(TBq/g)	(Ci/g)
Rh-102		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{1}$	$1.2X10^{3}$
Rh-102m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Rh-103m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$1.2X10^{6}$	$3.3X10^{7}$
Rh-105		$1.0X10^{1}$	$2.7X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{4}$	$8.4X10^{5}$
Rn-222 (a)	Radon (86)	$3.0X10^{-1}$	8.1	$4.0X10^{-3}$	$1.1X10^{-1}$	$5.7X10^{3}$	$1.5X10^{5}$
Ru-97	Ruthenium (44)	5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.7X10^{4}$	$4.6X10^{5}$
Ru-103 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Ru-105		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{5}$	$6.7X10^{6}$
Ru-106 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.3X10^{3}$
S-35	Sulphur (16)	$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{3}$	$4.3X10^{4}$
Sb-122	Antimony (51)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Sb-124		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.5X10^{2}$	$1.7X10^{4}$
Sb-125		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$3.9X10^{1}$	$1.0X10^{3}$
Sb-126		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Sc-44	Scandium (21)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.7X10^{5}$	$1.8X10^{7}$
Sc-46		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.3X10^{3}$	$3.4X10^{4}$
Sc-47		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.1X10^{4}$	$8.3X10^{5}$
Sc-48		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.5X10^{4}$	$1.5X10^{6}$
Se-75	Selenium (34)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$5.4X10^{2}$	$1.5X10^{4}$
Se-79		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$2.6X10^{-3}$	$7.0X10^{-2}$
Si-31	Silicon (14)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.4X10^{6}$	$3.9X10^{7}$
Si-32		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	3.9	$1.1X10^{2}$
Sm-145	Samarium (62)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.8X10^{1}$	$2.6X10^{3}$
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5X10^{-1}$	$2.3X10^{-8}$
Sm-151		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.7X10^{-1}$	$2.6X10^{1}$
Sm-153		9.0	$2.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.6X10^{4}$	$4.4X10^{5}$
Sn-113 (a)	Tin (50)	4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$3.7X10^{2}$	$1.0X10^{4}$
Sn-117m		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$

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						(TBq/g)	(Ci/g)
Sn-119m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Sn-121m (a)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	2.0	$5.4X10^{1}$
Sn-123		$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Sn-125		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{3}$	$1.1X10^{5}$
Sn-126 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.8X10^{-2}$
Sr-82 (a)	Strontium (38)	$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.3X10^{3}$	$6.2X10^{4}$
Sr-85		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.8X10^{2}$	$2.4X10^{4}$
Sr-85m		5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.2X10^{6}$	$3.3X10^{7}$
Sr-87m		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$4.8X10^{5}$	$1.3X10^{7}$
Sr-89		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.9X10^{4}$
Sr-90 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	5.1	$1.4X10^{2}$
Sr-91 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Sr-92 (a)		1.0	$2.7X10^{1}$	$3.0X10^{-1}$	8.1	$4.7X10^{5}$	$1.3X10^{7}$
T(H-3)	Tritium (1)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.6X10^{2}$	$9.7X10^{3}$
Ta-178 (long-lived)	Tantalum (73)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$4.2X10^{6}$	$1.1X10^{8}$
Ta-179		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.1X10^{1}$	$1.1X10^{3}$
Ta-182		$9.0X10^{-1}$	$2.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Tb-157	Terbium (65)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-158		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-160		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{2}$	$1.1X10^{4}$
Tc-95m (a)	Technetium (43)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.3X10^{2}$	$2.2X10^{4}$
Tc-96		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.2X10^{4}$	$3.2X10^{5}$
Tc-96m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.4X10^{6}$	$3.8X10^{7}$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2X10^{-5}$	$1.4X10^{-3}$
Tc-97m		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.6X10^{2}$	$1.5X10^{4}$
Tc-98		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.2X10^{-5}$	$8.7X10^{-4}$
Tc-99		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.3X10^{-4}$	$1.7X10^{-2}$
Tc-99m		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$1.9X10^{5}$	$5.3X10^{6}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Te-121	Tellurium (52)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.4X10^{3}$	$6.4X10^{4}$
Te-121m		5.0	$1.4X10^{2}$	3.0	$8.1X10^{1}$	$2.6X10^{2}$	$7.0X10^{3}$
Te-123m		8.0	$2.2X10^{2}$	1.0	$2.7X10^{1}$	$3.3X10^{2}$	$8.9X10^{3}$
Te-125m		$2.0X10^{1}$	$5.4X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.7X10^{2}$	$1.8X10^{4}$
Te-127		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.8X10^{4}$	$2.6X10^{6}$
Te-127m (a)		$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
Te-129		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{5}$	$2.1X10^{7}$
Te-129m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Te-131m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{4}$	$8.0X10^{5}$
Te-132 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.1X10^{4}$	$3.0X10^{5}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-3}$	$1.4X10^{-1}$	$1.1X10^{3}$	$3.1X10^{4}$
Th-228 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.0X10^{1}$	$8.2X10^{2}$
Th-229		5.0	$1.4X10^{2}$	$5.0X10^{-4}$	$1.4X10^{-2}$	$7.9X10^{-3}$	$2.1X10^{-1}$
Th-230		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.6X10^{-4}$	$2.1X10^{-2}$
Th-231		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.0X10^{4}$	$5.3X10^{5}$
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0X10^{-9}$	$1.1X10^{-7}$
Th-234 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.6X10^{2}$	$2.3X10^{4}$
Th(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-9}$	$2.2X10^{-7}$
Ti-44 (a)	Titanium (22)	$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	6.4	$1.7X10^{2}$
Tl-200	Thallium (81)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Tl-201		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$7.9X10^{3}$	$2.1X10^{5}$
Tl-202		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.0X10^{3}$	$5.3X10^{4}$
Tl-204		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.7X10^{1}$	$4.6X10^{2}$
Tm-167	Thulium (69)	7.0	$1.9X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{3}$	$8.5X10^{4}$
Tm-170		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{2}$	$6.0X10^{3}$
Tm-171		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$
U-230 (fast lung absorption) (a)(d)	Uranium (92)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-1}$	2.7	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (medium lung		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.0X10^{3}$	$2.7X10^{4}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
absorption) (a)(e)							
U-230 (slow lung absorption) (a)(f)		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$1.0X10^{3}$	$2.7X10^{4}$
U-232 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-233 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-234 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-235 (all lung absorption types) (a),(d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$8.0X10^{-8}$	$2.2X10^{-6}$
U-236 (fast lung absorption) (d)		Unlimited	Unlimited	Unlimited	Unlimited	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-238 (all lung absorption types) (d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$1.2X10^{-8}$	$3.4X10^{-7}$
U (nat)		Unlimited	Unlimited	Unlimited	Unlimited	$2.6X10^{-8}$	$7.1X10^{-7}$
U (enriched to 20% or less) (g)		Unlimited	Unlimited	Unlimited	Unlimited	See Table 257-6	See Table 257-6

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	See Table 257-6	(See Table 257-5)
V-48	Vanadium (23)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$6.3X10^{3}$	$1.7X10^{5}$
V-49		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{2}$	$8.1X10^{3}$
W-178 (a)	Tungsten (74)	9.0	$2.4X10^{2}$	5.0	$1.4X10^{2}$	$1.3X10^{3}$	$3.4X10^{4}$
W-181		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$2.2X10^{2}$	$6.0X10^{3}$
W-185		$4.0X10^{1}$	$1.1X10^{3}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
W-187		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
W-188 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{-1}$	8.1	$3.7X10^{2}$	$1.0X10^{4}$
Xe-122 (a)	Xenon (54)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.8X10^{4}$	$1.3X10^{6}$
Xe-123		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.4X10^{5}$	$1.2X10^{7}$
Xe-127		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$1.0X10^{3}$	$2.8X10^{4}$
Xe-131m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.1X10^{3}$	$8.4X10^{4}$
Xe-133		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$6.9X10^{3}$	$1.9X10^{5}$
Xe-135		3.0	$8.1X10^{1}$	2.0	$5.4X10^{1}$	$9.5X10^{4}$	$2.6X10^{6}$
Y-87 (a)	Yttrium (39)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.7X10^{4}$	$4.5X10^{5}$
Y-88		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$5.2X10^{2}$	$1.4X10^{4}$
Y-90		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{4}$	$5.4X10^{5}$
Y-91		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.1X10^{2}$	$2.5X10^{4}$
Y-91m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.5X10^{6}$	$4.2X10^{7}$
Y-92		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.6X10^{5}$	$9.6X10^{6}$
Y-93		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.2X10^{5}$	$3.3X10^{6}$
Yb-169	Ytterbium (70)	4.0	$1.1X10^{2}$	1.0	$2.7X10^{1}$	$8.9X10^{2}$	$2.4X10^{4}$
Yb-175		$3.0X10^{1}$	$8.1X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.6X10^{3}$	$1.8X10^{5}$
Zn-65	Zinc (30)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Zn-69		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{6}$	$4.9X10^{7}$
Zn-69m (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Zr-88	Zirconium (40)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Zr-93		Unlimited	Unlimited	Unlimited	Unlimited	$9.3X10^{-5}$	$2.5X10^{-3}$

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Zr-95 (a)		2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Zr-97 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$

[a] A_1 and/or A_2 values include contributions from daughter nuclides with half-lives less than 10 days.
[b] The values of A_1 and A_2 in Curies (Ci) are approximate and for information only; the regulatory standard units are Terabecquerels (TBq), (subsection (aa)(1) of this section - Determination of A_1 and A_2, Section I.).
[c] The quantity may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.
[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.
[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.
[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.
[g] These values apply to unirradiated uranium only.
[h] A_1 = 0.1 TBq (2.7 Ci) and A_2 = 0.001 TBq (0.027 Ci) for Cf-252 for domestic use.
[i] A_2 = 0.74 TBq (20 Ci) for Mo-99 for domestic use.

Figure: 25 TAC §289.257(aa)(7)
Table 257-4

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ac-225	Actinium (89)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ac-227		$1.0X10^{-1}$	$2.7X10^{-12}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ac-228		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-105	Silver (47)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-108m (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-110m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-111		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Al-26	Aluminum (13)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Am-241	Americium (95)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-242m (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-243 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ar-37	Argon (18)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ar-39		$1.0X10^{7}$	$2.7X10^{-4}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ar-41		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
As-72	Arsenic (33)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-73		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
As-74		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
As-76		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-77		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
At-211	Astatine (85)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-193	Gold (79)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-194		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-195		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-198		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-199		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-131	Barium (56)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ba-133m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-140 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Be-7	Beryllium (4)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Be-10		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-205	Bismuth (83)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-206		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-207		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bk-247	Berkelium (97)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Bk-249		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-76	Bromine (35)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Br-77		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-82		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-11	Carbon (6)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-14		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-41	Calcium (20)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-45		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-47		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-109	Cadmium (48)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-113m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-139	Cerium (58)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-141		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ce-143		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-144 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Cf-248	Californium (98)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-249		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-250		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-251		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-252		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-253		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-254		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cl-36	Chlorine (17)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cl-38		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-240	Curium (96)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cm-242		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-243		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-244		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-245		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-246		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-247		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-248		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Co-55	Cobalt (27)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Co-57		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Co-60		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cr-51	Chromium (24)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-129	Cesium (55)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-131		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cs-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Cs-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cs-134m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-135		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-136		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-137 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cu-64	Copper (29)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cu-67		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-159	Dysprosium (66)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Dy-165		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-166		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Er-169	Erbium (68)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Er-171		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-147	Europium (63)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-150 (short lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-150 (long lived)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-154		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-155		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-156		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
F-18	Fluorine (9)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-52	Iron (26)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-55		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-59		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-60		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-67	Gallium (31)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ga-68		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-72		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Gd-146	Gadolinium (64)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Gd-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Gd-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Gd-159		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ge-68	Germanium (32)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ge-71		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ge-77		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Hf-172	Hafnium (72)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-175		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-181		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-182		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-194	Mercury (80)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-197		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Hg-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166	Holmium (67)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-123	Iodine (53)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
I-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-125		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-126		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-131		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-133		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
I-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-135		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-111	Indium (49)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-113m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-114m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-115m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-189	Iridium (77)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ir-190		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-192		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ir-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
K-40	Potassium (19)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-42		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-43		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Kr-81	Krypton (36)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Kr-85		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{4}$	$2.7X10^{-7}$
Kr-85m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Kr-87		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
La-137	Lanthanum (57)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
La-140		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Lu-172	Lutetium (71)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Lu-173		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-177		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Mg-28	Magnesium (12)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-52	Manganese (25)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-53		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{9}$	$2.7X10^{-2}$
Mn-54		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Mn-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mo-93	Molybdenum (42)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Mo-99		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
N-13	Nitrogen (7)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Na-22	Sodium (11)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Na-24		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Nb-93m	Niobium (41)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Nb-94		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-97		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-147	Neodymium (60)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ni-59	Nickel (28)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-63		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-65		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Np-235	Neptunium (93)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (short-lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (long-lived)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Np-237 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Np-239		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-185	Osmium (76)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-191m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-193		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-32	Phosphorus (15)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-33		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pa-230	Protactinium (91)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Pa-231		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pa-233		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-201	Lead (82)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-202		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-205		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-210 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pb-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pd-103	Palladium (46)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-107		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-109		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-143	Promethium (61)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-144		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-145		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-147		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-148m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-149		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-151		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Po-210	Polonium (84)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pr-142	Praseodymium (59)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pr-143		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-188	Platinum (78)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-193		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-193m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Pu-236	Plutonium (94)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-237		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pu-238		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-239		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-240		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pu-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pu-242		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-244		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-223 (b)	Radium (88)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-224 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-225		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-226 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-228 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-81	Rubidium (37)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-83		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-84		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-86		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-87		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rb(nat)		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Re-184	Rhenium (75)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-184m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-186		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-187		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Re-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Re-189		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re(nat)		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Rh-99	Rhodium (45)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-101		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Rh-102		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-102m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-103m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Rh-105		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rn-222 (b)	Radon (86)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ru-97	Ruthenium (44)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ru-103		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-105		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-106 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
S-35	Sulphur (16)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sb-122	Antimony (51)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sb-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-44	Scandium (21)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-46		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-47		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-48		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Se-75	Selenium (34)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Se-79		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Si-31	Silicon (14)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Si-32		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sm-145	Samarium (62)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sm-147		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sm-151		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sm-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-113	Tin (50)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-117m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Sn-119m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-121m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-123		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sn-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-82	Strontium (38)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-85		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-85m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sr-87m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-89		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-90 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sr-91		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-92		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
T(H-3)	Tritium (1)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Ta-178 (long-lived)	Tantalum (73)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ta-179		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ta-182		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tb-157	Terbium (65)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tb-158		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tb-160		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-95m	Technetium (43)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-97		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Tc-97m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-98		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-99		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-99m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Te-121	Tellurium (52)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-121m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Te-123m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-125m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-127m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-129m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-131m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-132		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-228 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-229 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Th-230		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-231		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-232		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-234 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Th (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ti-44	Titanium (22)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Tl-200	Thallium (81)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-201		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-202		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-204		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tm-167	Thulium (69)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-170		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-171		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
U-230 (fast lung absorption) (b),(d)	Uranium (92)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
U-230 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-230 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (fast lung absorption) (b),(d)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U-232 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-233 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-234 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-235 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-236 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-238 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
U (enriched to 20% or less) (g)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (dep)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
V-48	Vanadium (23)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
V-49		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-178	Tungsten (74)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-181		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-185		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-187		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-122	Xenon (54)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-123		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-131m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-133		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-135		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Y-87	Yttrium (39)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-88		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-90		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-91		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-91m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-92		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-93		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Yb-169	Ytterbium (70)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Yb-175		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zn-65	Zinc (30)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Zr-88	Zirconium (40)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-93 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zr-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-97 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

[a][Reserved]

[b] Parent nuclides and their progeny included in secular equilibrium are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Cs-137	Ba-137m
Ce-134	La-134
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-20
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

[c][Reserved]

[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.

[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.

[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.

[g] These values apply to unirradiated uranium only.

Figure: 25 TAC §289.257(aa)(8)

Table 257-5: General Values For A_1 And A_2

Contents	A_1		A_2		Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limits for exempt consignments (Bq)	Activity limits for exempt consignments (Ci)
	(TBq)	(Ci)	(TBq)	(Ci)				
Only beta or gamma emitting radionuclides are known to be present	1×10^{-1}	2.7×10^{0}	2×10^{-2}	5.4×10^{-1}	1×10^{1}	2.7×10^{-10}	1×10^{4}	2.7×10^{-7}
Only alpha emitting radionuclides are known to be present	2×10^{-1}	5.4×10^{0}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}
No relevant data are available	1×10^{-3}	2.7×10^{-2}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}

Figure: 25 TAC §289.257(aa)(9)

Table 257-6: Activity-mass Relationships for Uranium

Uranium Enrichment* wt % U-235 present	Specific Activity TBq/g	Specific Activity Ci/g
0.45	$1.8x10^{-8}$	5.0×10^{-7}
0.72	$2.6x10^{-8}$	$7.1x10^{-7}$
1.0	$2.8x10^{-8}$	$7.6x10^{-7}$
1.5	$3.7x10^{-8}$	$1.0x10^{-6}$
5.0	$1.0x10^{-7}$	$2.7x10^{-6}$
10.0	$1.8x10^{-7}$	$4.8x10^{-6}$
20.0	$3.7x10^{-7}$	$1.0x10^{-5}$
35.0	$7.4x10^{-7}$	$2.0x10^{-5}$
50.0	$9.3x10^{-7}$	$2.5x10^{-5}$
90.0	$2.2x10^{-6}$	$5.8x10^{-5}$
93.0	$2.6x10^{-6}$	$7.0x10^{-5}$
95.0	$3.4x10^{-6}$	$9.1x10^{-5}$

* The figures for uranium include representative values for the activity of the uranium-235 which is concentrated during the enrichment process.

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.

Department of Aging and Disability Services

Public Notice Announcing Pre-application Orientation (PAO) for Enrollment of Medicaid Waiver Program Providers

The Department of Aging and Disability Services (DADS) will hold a Pre-Application Orientation (PAO) for persons seeking to participate as a program contractor in the Home and Community-Based Services (HCS) and/or the Texas Home Living (TxHmL) Medicaid Waiver Programs.

There will be a non-refundable processing fee of $25.00 per registering legal entity. Legal entities that do not attend the PAO will not receive a refund of the processing fee. This fee will cover two representatives per legal entity. No more than two representatives may attend and represent a legal entity. The processing fee must be submitted with the registration form either by money order or cashiers check payable to: Texas Department of Aging and Disability Services. **DADS will not accept cash or personal checks.**

In addition, DADS will no longer be accepting faxes or any other forms of written requests for the registration form. The registration form must be completed online. Persons wanting to attend the PAO must access the registration form from the DADS website at: http://www.dads.state.tx.us/forms/8629/. **The registration form will only be available on the DADS website beginning Tuesday, September 18, 2007, through Friday, November 16, 2007. The registration form must be completed, printed, signed by the authorized representative and returned to DADS.**

Registration forms received by DADS without the processing fee or original signatures **will not** be processed and attendance at the PAO **will not** be allowed. There will be **no exceptions.**

Persons wanting to attend the PAO must submit their registration form to DADS by mail or courier. Registration forms must be sent to:

Texas Department of Aging and Disability Services

Rodrick Pollock, Contract Specialist

Community Services Contracts (MC W-517)

P.O. Box 149030

Austin, Texas 78714-9030

The PAO will be held at 8:45 a.m., Monday, December 17, 2007, in Austin, Texas at the J. J. Pickle Center. **Registration will close promptly at 8:40 a.m. Arrivals after 8:40 a.m. will not be admitted, and will not receive a PAO Certificate of Attendance. (No Exceptions)**

To attend the PAO, an applicant must submit a completed registration form to DADS in a timely manner. A completed registration form is submitted timely only under the following conditions:

(1) if mailed via the US Postal Service, the completed registration form bears a postmark date no later than Friday, November 16, 2007;

(2) if sent via a common or contract carrier, a receipt by the carrier shows that it was placed in the hands of the carrier no later than Friday, November 16, 2007; or

(3) if hand delivered, it is delivered directly to the DADS, Community Services Contracts Unit, 701 W. 51st Street (MC W-517), Austin, Texas, no later than Friday, November 16, 2007.

Persons requiring an interpreter for the deaf or hearing impaired, or any other accommodation, must contact Rodrick Pollock at least 72 hours prior to the PAO at (512) 438- 5428.

For any additional information concerning the PAO, you may contact Art G. Gonzales, Program Specialist, at (512) 438-5737. Further information regarding the PAO application process may be obtained on the DADS website at: http://www.dads.state.tx.us/business/mental_retardation/hcs/index.html.

Criminal History Record Information

In accordance with 42 Code of Federal Regulations (CFR) §455.106, all applicants must disclose to DADS criminal history record information about "all persons with an ownership or control interest" in the applicant, or an "agent" or "managing employee" of the applicant. Submission of the criminal history record information will be required with the DADS *Application for Participation.*

National Provider Identifier

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 requires health care entities to begin using National Provider Identifiers (NPI) on standard health care transactions. DADS is requiring all health care entities applying to contract with DADS to obtain and report their NPI number. You will be required to submit a NPI assignment letter or email from the National Plan and Provider Enumeration System (NPPES), along with your *Application for Participation* packet, which will be provided at the PAO.

In order to comply with this HIPAA requirement, effective December 1, 2006, all new contract applicants must obtain and report their NPI number with their contract application.

TRD-200704002

Kenneth L. Owens

General Counsel

Department of Aging and Disability Services

Filed: August 30, 2007

♦ ♦ ♦

Texas Department of Agriculture

Request for Proposals: Texas Agricultural Finance Authority Financial Advisor

1. Purpose.

The Texas Agricultural Finance Authority (the Authority), a public authority established within the Texas Department of Agriculture (the Department), seeks proposals in response to this Request for Proposals (RFP) from firms with the qualifications and experience required to provide financial advisory services to the Authority. This RFP is issued for the purpose of selecting a financial advisor for all financing matters as described herein.

The Authority reserves the right to select one or more co-financial advisors from firms that respond to this RFP. The Authority's decision to select a co-financial advisor, if any, will be determined by the evaluation of the responses to the RFP. Please indicate in Part 1 of your response whether your firm would like to serve as only a financial advisor, only a co-financial advisor, or either.

2. Background of the Authority.

The Authority was created by the Texas Legislature under Texas Agriculture Code (the Code), Chapter 58, for the purpose of financing innovative, diversified, or value-added production, processing, marketing, or exporting businesses in Texas and for providing financial assistance for other rural economic development activities. 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 Authority provides financing alternatives through instruments including direct loans, loan guaranties, loan participation, insurance or co-insurance.

Chapter 58 and Chapter 59 of the Code provide for the issuance by the Authority of revenue bonds and general obligation bonds. 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.

The Board may approve eligible borrowers for financing through direct loans, loan guaranties, loan participation, direct issuance of obligations, or other financial instruments.

3. Scope of Services.

Upon request, the financial advisor is to be responsible for all duties and services necessary or advisable to facilitate the issuance of bonds and other obligations, including but not limited to: devising and recommending to the Board a plan of financing for bonds to be issued, which plan shall include a maturity schedule and other terms and conditions, as well result in the most advantageous terms to the Authority, consistent with a minimum effective interest rate; determining the timing of the offering and the sizing of the issue; participating in document preparation and assisting bond counsel in the coordination of the offering; preparing such information, as necessary, for the rating agencies and upon Authority approval, assisting in the presentation to such agencies; assisting the Authority in maintaining on-going relationships with the credit rating agencies; participation in public offering statement (POS) and offering statement (OS) preparation and delivery of a camera- ready copy to the printer; advising the Authority concerning the need for credit enhancement and assisting in the negotiations regarding such; assisting in the approval process of the Bond Review Board and any other agency as necessary to the issuance of the bonds; assisting in closing details and post-closing duties, including the development of a final report to the Bond Review Board to include a verification of all costs of issuance and preparation of a complete bond transcript; answering questions or requests for additional information from prospective purchasers; evaluating any bids submitted for the purchase of the bonds; advising the Authority with respect to the investment of bonds proceeds and the accounting of arbitrage earnings; assisting the Authority in providing information to various legislators and other state agencies; advising the staff of the Authority and the Board of ongoing development in the bond industry as they affect the Authority; soliciting bids for, contracting with, and paying on behalf of the Authority, fees associated with the printing of bond offering documents, ratings, trustee and paying agent fees and related services when necessary; monitoring and controlling the costs of fees and expenses incurred in connection with the issuance of the bonds; monitoring, suggesting and advising the Authority on refunding opportunities, derivatives and other financial products that would help the Authority lower its cost of borrowing; and all other matters necessary or incidental to the issuance and administration of debt obligations.

In addition, the financial advisor shall advise the Authority on any matters that might have an affect on the Authority or any of its outstanding issues. The Authority will be responsible for allocating duties and tasks between the Financial Advisor and Co-Financial Advisor, if any, commensurate with level of compensations.

The financial advisor and co-financial advisor, if any, will not be permitted to underwrite any portion of an issue or program for the Authority during the term of employment.

4. Form of Response.

a. Overview of the Firm.

Provide a description of the firm, including general experience and history in public finance, date founded, number of offices, location and number of professionals and employees in each office, total number of employees and professionals in the firm, description of specialty practice areas and firm philosophy. Describe structure of firm ownership (e.g., publicly held corporation, partnership, etc.) and any parents, affiliates, or subsidiaries of the firm.

b. Qualifications.

List the experience since January 1, 1997, of the firm and/or professionals proposed to be assigned to the Authority (see number 6 below also), as financial advisor, financial consultant, or senior manager on a negotiated underwriting for the following types of issuers and issues. If listing experience of a professional while at a different firm, please specify the name of the firm. Please include the name of the issuer, title of the bonds, date of the bonds, par amount of the issue, type of sale, and role the firm played. Tabular format is acceptable.

By Issuer Type as follows: State of Texas issuers; Other issuers in the State of Texas; Regional authorities and state-level issuers in states other than Texas.

By Issue Type as follows: State level General Obligation Bonds; State Revenue Bonds; Tax Exempt Commercial Paper; Taxable Commercial Paper.

Please select one transaction from the above list that you feel best demonstrates your ability to serve the Authority and describe in detail the financial issues involved in the transaction and your firm's approach to the analysis. (Please limit your discussion to no more than two pages.)

c. Other Experience.

Please describe your experience with respect to the following topics. Include any specific suggestions or practices that as financial advisor you would recommend for the Authority. The topics are: arbitrage compliance; continuing disclosure compliance; investor relation programs; interest rate swaps and other derivatives.

d. Bond Sale Pricing.

Describe the steps your firm would take as financial advisor to ensure the bidding process on competitive sales and the pricing process on negotiated sales renders the lowest true interest cost for the Authority.

What role do you suggest the Authority play in organizing the sales effort of the bonds (i.e., establishing priority of orders, designation

rules, etc.)? What techniques would be most effective for the State to achieve its HUB participation goals on competitive and negotiated transactions? What techniques would you employ to evaluate senior and co-manager performance on a specific transaction?

e. Credit Relations.

Describe your firm's proposed approach to maintaining rating agency relationships for the Authority.

Describe your firm's recommended approach, if any, to developing and maintaining investor relations programs. Address the costs and benefits of such programs and how they relate to continuing disclosure requirements.

f. Resumes.

Provide brief resumes for those individuals who would be assigned to serve the Authority. Indicate the individuals' years of experience in public finance, any relevant licenses they hold, and how any particular area of expertise would benefit the Authority. Specify who would be assigned as the primary day-to- day contact for the Authority and indicated the role they played in the transactions listed above.

g. Business Practices.

Please describe your firm's previous experience and involvement working with Historically Underutilized Businesses (HUB) certified firms (if your firm is not HUB certified) or as a HUB certified firm, in a co-financial advisor relationship. Please describe your firm's approach to working with co-financial advisor, including level of effort, and division of duties.

Please describe efforts made by your firm to encourage and develop the participation of minorities and women in your firm's provision of financial advisory services or underwriting, if any.

h. Conflict of Interest.

Please disclose any conflicts of interest. Disclose all contractual or informal business arrangement/agreements, including fee arrangements and consulting agreements between your Firm and the Authority, its staff and/or its Board, or any entity that provides services to the Authority.

i. References.

Please provide names, addresses, and phone numbers of at least two references.

j. Fee Structure.

Please provide your fee structure, including if applicable, hourly rates, a per transaction maximum on hourly fees, flat fees, and a per transaction cap on expenses (not to be exceeded without prior approval from the Authority). Fees based on a percentage of the par amount of the bonds or on a per bond basis are discouraged.

5. Term of Agreement.

The contract term is to be for a period beginning with the date of hiring by the Authority to October 31, 2008. The Board may renew the contract, at its option, for up to (2) additional terms of one (1) year each. The Board retains the right to terminate the contract for any reason and at any time, upon the payment of then earned fees and expenses.

6. Proposal Modification.

Any proposal 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 proposed due date; however, non-substantive correction or deletions may be made with the approval of the Authority. The Authority also reserves the right to make amendments to the RFP by giving written notice to all firms who receive the RFP and publishing notice thereof in the *Texas Register*.

7. Time Schedule.

Proposals are due no later than 5:00 p.m. on October 15, 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 unbound original and three (3) copies of their proposal to: Mr. Rick Rhodes, Assistant Commissioner for Rural Economic Development, **IN RESPONSE TO RFP: FINANCIAL ADVISOR**, Texas Agricultural Finance Authority, c/o Texas Department of Agriculture, P.O. Box 12847, Austin, Texas 78711, Street, Address: 1700 N. Congress, Stephen F. Austin Bldg., 10th Floor, Austin, Texas 78701.

A duly authorized representative of the firm must execute the submitted RFP response. An unsigned proposal will not be accepted. All proposals become the property of the Authority. Proposals must set forth accurate and complete information as required by this RFP. Oral instruction of offers will not be considered. Contact with Board Members regarding this RFP is expressly prohibited and will result in disqualification of your proposal. Questions regarding this RFP should be submitted, in writing, to Mr. Rick Rhodes, assistant commissioner for rural economic development, at the address listed above or by fax, (888) 216-9867.

8. Basis of Award.

Department staff designated to administer the Authority programs will review the proposals as directed by the Board. The selection will be based on demonstrated competence, experience, knowledge and qualifications, as well as the reasonableness of the proposed fee.

Firms responding are encouraged to maintain a Texas office staffed with personnel who are responsible for providing financial advisory services to the Authority. By this RFP, however, the Authority has not committed itself to employ a financial advisor nor does the suggested scope of service or term of agreement below require that the financial advisor be employed for any or all of those purposes. The Authority reserves the right to make those decisions after receipt of proposals and the Authority's decision on these matters is final.

The Authority reserves the right to negotiate individual elements of any proposal and to reject any and all proposals.

9. Cost Incurred in Responding.

All costs directly or indirectly related to preparation of a response to the RFP or any oral presentation required to supplement and/or clarify the RFP which may be required by the Authority shall be the sole responsibility of, and shall be borne by the applicant.

10. Release of Information and Open Records.

All proposals shall be deemed, once submitted, to be the property of the Authority and subject to the Texas Public Information Act (the Act). Under the Act, information submitted in response to this RFP may not be released by the Authority during the proposal evaluation process or prior to the awarding of a contract. After the evaluation process is completed by the Authority and a contract is awarded, proposals and information included therein may be subject to public disclosure under the Act.

TRD-200704080

Dolores Alvarado Hibbs
General Counsel
Texas Department of Agriculture
Filed: September 5, 2007

♦ ♦ ♦

Office of the Attorney General

Request for Applications (RFA) for the Sexual Assault Prevention and Crisis Services (SAPCS-Federal) Program

The Crime Victim Services Division (CVSD) of the Office of the Attorney General (OAG) is soliciting local and statewide applications from programs that wish to utilize SAPCS-Federal funds for projects that support the primary prevention of sexual assault or sexual violence.

Applicable Funding Source: The source of federal funds includes the Federal Department of Health and Human Services, Preventative Health and Health Services Block Grant, Catalog of Federal Domestic Assistance (CFDA) Number 93.991 and Injury Prevention and Control Research and State and Community Based Programs, CFDA Number 93.136. The federal funds are used for grant contracts supporting the prevention of sexual assault or sexual violence. All funding is contingent upon the appropriation of funds by the United States Congress and the Texas Legislature. The OAG makes no commitment that an application, once submitted, or a grant, once funded, will receive subsequent funding.

Eligibility Requirements: Only agencies that have not already received an SAPCS-Federal award for FY2008 are eligible to apply. Eligible applicants are: local units of government, excluding law enforcement agencies and prosecutor's offices; non-profit agencies with 26. U.S.C. 501(c)(3) status; and state agencies.

Local Programs: Eligible local programs must meet the local program eligibility requirements for a SAPCS-State grant, which means the local program must offer the following minimum services for at least nine months prior to receiving an SAPCS grant contract: 24-hour crisis hotline; crisis intervention; public education; advocacy and accompaniment to hospitals, law enforcement offices, prosecutor's offices, and courts for survivors and their family members; and crisis intervention volunteer training.

Statewide Program: A statewide program, to be eligible for special project funding, must show that it supports efforts to maintain or expand existing services offered by local sexual assault programs; improves services to survivors; or other activities consistent with Texas Government Code, Chapter 420.

Eligibility: The OAG will initially screen each application for eligibility. Applications will be deemed ineligible if the application is submitted by an ineligible applicant; the application is not filed in the manner and form required by the RFA; the application is filed after the deadline established in the RFA; or the application does not meet other requirements as stated in the RFA and the Application Kit.

How to Obtain Application Kit: The OAG will post the Application Kit on the OAG's official agency Web site at http://www.oag.state.tx.us/victims/grants2008.shtml. Updates and other helpful reminders about the application process will also be posted at this location. Potential applicants are encouraged to refer regularly to this Web site.

Deadlines and Filing Instructions for the Grant Application:

Deadline: Applicants must submit their application, including all required attachments, to the OAG and the OAG must receive the submitted application and all required attachments by 5:00 p.m. CST October 5, 2007 to be considered timely filed.

Filing Instructions: **To meet the deadline, the applicant must submit both paper (hard copies) and electronic (e-mail) documents.** An application will be considered filed when the OAG receives the paper (hard copies) and the electronic (e-mail) application in the following ways by the required deadline:

(1) Paper (hard copies) - Via Next Day Air Overnight delivery service (Federal Express, United Parcel Service, DHL or Lone Star):

The applicant must submit one original and three hard copies of the complete application (Excel workbook and all attachments).

The complete application (Excel workbook and all attachments) must be sent to the following address:

CVS GRANTS APPLICATIONS - MC 005

OFFICE OF THE ATTORNEY GENERAL

300 W. 15th St. Room 102

Austin, TX 78701-1649

The original and three hard copies must be received by 5:00 p.m. CST on October 5, 2007.

Applications hand-delivered by the applicant or submitted via any kind of same day courier service will not be accepted.

(2) Electronic - Via e-mail:

The applicant must submit the Excel workbook.

The Excel workbook must be sent to the following e-mail address: CVSGrantsApplications@oag.state.tx.us

The e-mail must be received by 5:00 p.m. CST on October 5, 2007.

The OAG will not consider an application if it is not filed by the due date, 5:00 p.m. CST on October 5, 2007.

Minimum and Maximum Amounts of Funding Available: The minimum amount of funding all programs may apply for is $20,000 per fiscal year. The maximum amounts of funding are as follows: new local or statewide programs--$25,000 per fiscal year; currently funded local programs--$100,000 per fiscal year; and currently funded statewide programs--$300,000 per fiscal year.

Regardless of the maximums stated above, a program may not apply, per fiscal year, for an amount higher than the SAPCS-Federal funds it received in FY2007. The amount of an award is determined solely by the OAG. The OAG may award grants at amounts above or below the established funding levels and is not obligated to fund a grant at the amount requested.

Start Date and Length of Grant Contract Period: The grant contract period (term) is up to eighteen months from December 1, 2007 through August 31, 2009, subject to and contingent upon funding and/or OAG approval.

No Match Requirements: There are no match requirements for SAPCS-Federal projects.

Volunteer Requirements: All SAPCS-Federal projects must have a volunteer component. Specific requirements for the volunteer component will be stated in the Application Kit.

Award Criteria: The OAG will make funding decisions that support the efficient and effective use of public funds. Scoring components will include, but are not limited to, information provided by the applicant on the proposed project activities and budget.

SAPCS Purpose Area: The purpose of the SAPCS-Federal program is to fund strategies and activities that support the primary prevention

of sexual assault or sexual violence and any other purposes consistent with Texas Government Code, Chapter 420.

Staffing: The funding priority for the SAPCS-Federal program is to support positions that work towards the development and implementation of primary prevention strategies and activities. All SAPCS-Federal projects must:

(a) Include a minimum of 75% of an applicant's budget in the personnel and fringe budget categories.

(b) Designate and request funding for a Primary Prevention Coordinator that is responsible for the development and implementation of primary prevention strategies and activities. This position must, at a minimum, work 20 hours per week on primary prevention activities.

In addition, only those staff positions that are directly related to achieving the goals of this project will be funded (this includes staff that has direct involvement in the planning, implementation, or delivery of project activities and those who directly supervise such staff).

Preference: The OAG reserves the right to consider all other appropriations or funding an applicant currently receives when making funding decisions. The OAG may give priority to applicants that do not receive other sources of funding, including funding that originates from the Texas Compensation to Victims of Crime Fund. The OAG reserves the right to give priority to programs that provide services in certain geographic or programmatic areas.

Prohibitions on Use of Grant Funds: OAG grant funds may not be used to support or pay the costs of overtime, dues, or lobbying; any portion of the salary or any other compensation for an elected government official; the purchase of food and beverages except as allowed under Texas State Travel Guidelines; the purchase or lease of vehicles; the purchase of promotional items or recreational activities; costs of travel that are unrelated to the direct delivery of services that support the OAG funded program; the costs for consultants or vendors who participate directly in writing a grant application; or for any unallowable costs set forth in applicable state or federal law, rules, regulations, guidelines, policies, procedures or cost principles. Grant funds may not be used to purchase any other products or services the OAG identifies as inappropriate or unallowable within this RFA or the Application Kit. Additional prohibitions include, but are not limited to, using grant funds for: construction and/or renovation; development of major software applications; administrative costs and/or personnel; direct counseling, treatment, or advocacy services to victims or perpetrators of sexual violence; media or awareness campaigns that exclusively promote awareness of where to receive victim services; research; and out-of-state travel for local programs.

OAG Contact Person: If additional information is needed, contact Sheila Hall at CVSGrantsApplications@oag.state.tx.us or (512) 936-6397.

TRD-200704068
Stacey Napier
Deputy Attorney General
Office of the Attorney General
Filed: September 4, 2007

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Request for Applications (RFA) for the Sexual Assault Prevention and Crisis Services (SAPCS-State) Program

The Crime Victim Services Division (CVSD) of the Office of the Attorney General (OAG) is soliciting local and statewide applications from programs that provide services to victims of sexual assault.

Applicable Funding Source: The source of state funds is a biennial appropriation by the Texas Legislature; these funds are constitutionally dedicated. Texas Code of Criminal Procedure, Article 56.541(e) authorizes the OAG to use money appropriated from the Texas Compensation to Victims of Crime Fund for grant contracts supporting victim-related services or assistance. Additional funding comes from parole fees pursuant to Texas Code of Criminal Procedure, Article 42.12, Section 19(e) and Texas Government Code, Section 508.189. All funding is contingent upon an appropriation to the OAG by the Texas Legislature. The OAG makes no commitment that an application, once submitted, or a grant, once funded, will receive subsequent funding.

Eligibility Requirements: Only agencies that have not already received an SAPCS-State award for FY2008 are eligible to apply. Eligible applicants are: local units of government, excluding law enforcement agencies and prosecutor's offices; non-profit agencies with 26. U.S.C. 501(c)(3) status; and state agencies.

Local Programs: A local program must offer the following minimum services for at least nine months prior to receiving a SAPCS-State grant contract: 24-hour crisis hotline; crisis intervention; public education; advocacy and accompaniment to hospitals, law enforcement offices, prosecutor offices, and courts for survivors and their family members; and crisis intervention volunteer training.

Statewide Program: A statewide program, to be eligible for special project funding, must show that it supports efforts to maintain or expand existing services offered by local sexual assault programs; improve services to survivors; or other activities consistent with Texas Government Code, Chapter 420.

Eligibility: The OAG will initially screen each application for eligibility. Applications will be deemed ineligible if the application is submitted by an ineligible applicant; the application is not filed in the manner and form required by the RFA; the application is filed after the deadline established in the RFA; or the application does not meet other requirements as stated in the RFA and the Application Kit.

How to Obtain Application Kit: The OAG will post the Application Kit on the OAG's official agency Web site at http://www.oag.state.tx.us/victims/grants2008.shtml. Updates and other helpful reminders about the application process will also be posted at this location. Potential applicants are encouraged to refer regularly to this Web site.

Deadlines and Filing Instructions for the Grant Application:

Deadline: Applicants must submit their application, including all required attachments, to the OAG and the OAG must receive the submitted application and all required attachments by 5:00 p.m. CST October 5, 2007 to be considered timely filed.

Filing Instructions: To meet the deadline, the applicant must submit both paper (hard copies) and electronic (e-mail) documents. An application will be considered filed when the OAG receives the paper (hard copies) and the electronic (e-mail) application in the following ways by the required deadline:

(1) Paper (hard copies) - Via Next Day Air Overnight delivery service (Federal Express, United Parcel Service, DHL or Lone Star): The applicant must submit one original and three hard copies of the complete application (Excel workbook and all attachments). The complete application (Excel workbook and all attachments) must be sent to the following address:

CVS Grants Applications - MC 005

Office of the Attorney General

300 W. 15th St. Room 102

Austin, TX 78701-1649

The original and three hard copies must be received by 5:00 p.m. CST on October 5, 2007.

Applications hand-delivered by the applicant or submitted via any kind of same day courier service will not be accepted.

(2) Electronic - Via e-mail:

The applicant must submit the Excel workbook.

The Excel workbook must be sent to the following e-mail address: CVSGrantsApplications@oag.state.tx.us

The e-mail must be received by 5:00 p.m. CST on October 5, 2007.

The OAG will **NOT** consider an Application if it is not filed by the due date, 5:00 p.m. CST on October 5, 2007.

Minimum and Maximum Amounts of Funding Available: The minimum amount of funding all programs may apply for is $20,000 per fiscal year. The maximum amounts of funding are as follows: new local or statewide programs--$30,000 per fiscal year; currently funded local programs--$200,000 per fiscal year; and currently funded statewide programs--$300,000 per fiscal year.

Regardless of the maximums stated above, a program may not apply, per fiscal year, for an amount higher than the SAPCS-State funds it received in FY2007. The amount of an award is determined solely by the OAG. The OAG may award grants at amounts above or below the established funding levels and is not obligated to fund a grant at the amount requested.

Start Date and Length of Grant Contract Period: The grant contract period (term) is up to eighteen (18) months from December 1, 2007 through August 31, 2009, subject to and contingent upon funding and/or OAG approval.

No Match Requirements: There are no match requirements for SAPCS-State projects.

Volunteer Requirements: All SAPCS-State projects must have a volunteer component. Specific requirements for the volunteer component will be stated in the Application Kit.

Award Criteria: The OAG will make funding decisions that support the efficient and effective use of public funds. Scoring components will include, but are not limited to, information provided by the applicant on the proposed project activities and budget.

SAPCS Purpose Area: The purpose of the SAPCS-State program is to maintain or expand the existing services of local sexual assault programs and any other purposes consistent with Texas Government Code, Chapter 420.

Staffing: All SAPCS-State projects must:

(a) Include one direct service staff person working at least 20 hours per week or two direct service staff persons working at least 10 hours each per week in the applicant's budget.

(b) Include a minimum of 75% of an applicant's budget in the personnel and fringe budget categories.

In addition, an applicant may not include more than three administrative positions providing administrative support to the SAPCS-State project.

Preference: The OAG reserves the right to consider all other appropriations or funding an applicant currently receives when making funding decisions. The OAG may give priority to applicants that do not receive other sources of funding, including funding that originates from the Texas Compensation to Victims of Crime Fund. The OAG reserves the right to give priority to programs that provide services in certain geographic or programmatic areas.

Prohibitions on Use of Grant Funds: OAG grant funds may not be used to support or pay the costs of overtime, dues, or lobbying; any portion of the salary or any other compensation for an elected government official; the purchase of food and beverages except as allowed under Texas State Travel Guidelines; the purchase or lease of vehicles; the purchase of promotional items or recreational activities; out-of-state travel or costs of travel that are unrelated to the direct delivery of services that support the OAG funded program; the costs for consultants or vendors who participate directly in writing a grant application; or for any unallowable costs set forth in applicable state or federal law, rules, regulations, guidelines, policies, procedures or cost principles. Grant funds may not be used to purchase any other products or services the OAG identifies as inappropriate or unallowable within this RFA or the Application Kit.

OAG Contact Person: If additional information is needed, contact Sheila Hall at CVSGrantsApplications@oag.state.tx.us or (512) 936-6397.

TRD-200704067
Stacey Napier
Deputy Attorney General
Office of the Attorney General
Filed: September 4, 2007

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Coastal Bend Workforce Development Board

Request for Proposal - Career Center Operation and Management

Using the Request for Proposals (RFP) method of procurement, the Coastal Bend Workforce Development Board, d.b.a. WorkSource, is soliciting proposals for the management and operation of its Workforce Centers for Program Year 2007. The Coastal Bend region consists of Aransas, Bee, Brooks, Duval, Jim Wells, Kenedy, Kleberg, Live Oak, McMullen, Nueces, Refugio, and San Patricio Counties.

The Workforce Service Delivery System incorporates at a minimum, general workforce information and referral; customer, employer, and job seeker services; customer intake, eligibility and assessment; case management; training, job placement; counseling, support services, follow-up, and retention services as funded by the Workforce Investment Act, Temporary Assistance to Needy Families/Choices, Food Stamps Employment Retention and Advancement Project, Wagner Peyser, Veterans, and Reintegration of Offenders (RIO) for the 12 county area.

Interested parties may obtain a copy of the RFP by calling or e-mailing Blair McDavid at (361) 225-1098, Ext.109 or blair.mcdavid@coastalworksource.com on Tuesday, September 4, 2007.

The deadline for receipt of proposals is Wednesday, October 10, 2007, at 12:00 noon CST. Proposals should be addressed to WorkSource, attention Blair McDavid, Procurement Manager, 400 Mann Street, Suite 1000, Corpus Christi, Texas 78401. Proposals received without the proper forms or after the deadline, will not be considered. Mailed or hand delivered responses are acceptable. Faxed or e-mailed copies will not be considered.

WorkSource is an Equal Opportunity employer/program. Historically Underutilized Businesses (HUBs) are encouraged to apply. Auxiliary aids and services are available upon request to individuals with disabilities. Telephone access is available by dialing 711.

TRD-200704085

Blair McDavid
Manager of Facilities and Procurement
Coastal Bend Workforce Development Board
Filed: September 5, 2007

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Request for Proposal for Youth Services

Using the Request for Proposals (RFP) method of procurement, the Coastal Bend Workforce Development Board, d.b.a. WorkSource, is soliciting proposals for delivery of Youth services within WorkSource's Workforce Centers for Program Year 2007. The Coastal Bend region consists of Aransas, Bee, Brooks, Duval, Jim Wells, Kenedy, Kleberg, Live Oak, McMullen, Nueces, Refugio, and San Patricio Counties.

The Board is soliciting proposals from qualified organizations to provide Youth program services for in-school and out-of-school youth ages 14 through 21 as authorized under Title I of the Workforce Investment Act, the Final Rule (20CFR) of the U.S. Department of Labor, Texas Workforce Commission rules and regulations, Board plan, and policies.

Youth service delivery will incorporate at a minimum general workforce information and referral; customer and job seeker services; customer intake, eligibility and assessment; case management; training, job placement; counseling, support services, follow-up, and retention services as funded by the Workforce Investment Act for the 12 county area.

Interested parties may obtain a copy of the RFP by calling or e-mailing Blair McDavid at (361) 225-1098, Ext.109 or blair.mcdavid@coastalworksource.com on Tuesday, September 4, 2007.

The deadline for receipt of proposals is Wednesday, October 10, 2007, at 12:00 noon CST. Proposals should be addressed to WorkSource, attention Blair McDavid, Procurement Manager, 400 Mann Street, Suite 1000, Corpus Christi, Texas 78401. Proposals received without the proper forms or after the deadline, will not be considered. Mailed or hand delivered responses are acceptable. Faxed or e-mailed copies will not be considered.

WorkSource is an Equal Opportunity employer/program. Historically Underutilized Businesses (HUB's) are encouraged to apply. Auxiliary aids and services are available upon request to individuals with disabilities. Telephone access is available by dialing 711.

TRD-200704086
Blair McDavid
Manager of Facilities and Procurement
Coastal Bend Workforce Development Board
Filed: September 5, 2007

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Comptroller of Public Accounts

Notice of Request for Proposals

Pursuant to Chapters 403 and 2254, Subchapter A, Texas Government Code, and Chapter 2305, §2305.038, Texas Government Code, the Comptroller of Public Accounts (Comptroller), State Energy Conservation Office (SECO), announces the issuance of its Request for Proposals (RFP #180e) from qualified, independent firms and institutions to provide professional energy engineering assistance and related services (Services) to public schools, hospitals, colleges, and universities for the Schools & Local Government Program (Program). One or more successful respondents will assist Comptroller in providing energy engineering assistance to public schools, hospitals, colleges, and universities as directed by Comptroller. Comptroller reserves the right to award one or more contracts under this RFP. The successful respondent(s), if any, will be expected to begin performance of the contract(s), if any, on or about October 16, 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 (Issuing Office), telephone number: (512) 305-8673, to obtain a copy of the RFP. The Comptroller will mail copies of the RFP only to those specifically requesting a copy. The RFP will be available for pick-up at the above-referenced address on or after Friday, September 14, 2007, after 10:00 a.m., Central Zone Time (CZT), and during normal business hours thereafter. Comptroller will also make the complete RFP available electronically on the Electronic State Business Daily (ESBD) after 10:00 a.m. (CZT), Friday, September 14, 2007.

All written inquiries, questions, and Non-Mandatory Letters of Intent to propose must be received in the Issuing Office prior to 2 p.m. (CZT) on Friday, September 21, 2007. Prospective respondents are encouraged to fax Letters of Intent and Questions to (512) 475-0973 to ensure timely receipt. The responses to questions and other information pertaining to this procurement will be posted on September 28, 2007, or as soon thereafter as practical, on the ESBD at: http://esbd.cpa.state.tx.us. Questions and inquiries received after the deadline will not be considered; respondents are solely responsible for verifying timely receipt in the Issuing Office of Non-Mandatory Letters of Intent and Questions.

Closing Date: Proposals must be received in the Issuing Office at the location specified above no later than 2 p.m. (CZT), on Friday, October 5, 2007. Proposals received in the Issuing Office after this time and date will not be considered; respondents are solely responsible for verifying timely receipt of Proposals in the Issuing Office.

Evaluation and Award Procedure: All proposals will be subject to evaluation by a committee based on the evaluation criteria and procedures set forth in the RFP. Comptroller will make the final decision. Comptroller reserves the right to accept or reject any or all proposals submitted. Comptroller is under no legal or other obligation to execute a contract on the basis of this notice or the distribution of any RFP. Comptroller shall pay for no costs incurred by any entity in responding to this notice or the RFP.

The anticipated schedule of events is as follows: Issuance of RFP - September 14, 2007; Non-Mandatory Letters of Intent and Questions Due - September 21, 2007, 2 p.m. CZT; Official Questions and Responses posted - September 28, 2007 (or as soon thereafter as practical); Proposals Due - October 5, 2007, 2 p.m. CZT; Contract Execution - October 16, 2007, or as soon thereafter as practical; Commencement of Project Activities - October 16, 2007, or as soon thereafter as practical.

TRD-200704087
Pamela Smith
Deputy General Counsel for Contracts
Comptroller of Public Accounts
Filed: September 5, 2007

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Office of Consumer Credit Commissioner

Correction of Error

The Finance Commission of Texas proposed new 7 TAC §89.101 and §89.102, concerning Property Tax Lenders. The notice appeared in the August 31, 2007, issue of the *Texas Register* (32 TexReg 5568).

Due to an error by the Texas Register, the agency's fax number was published instead of the telephone number on the last line of the notice

on page 5569. The last line should read: "For further information, please call: (512) 936-7640."

TRD-200704092

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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, 303.005, and 303.009, Texas Finance Code.

The weekly ceiling as prescribed by §303.003 and §303.009 for the period of 09/10/07 - 09/16/07 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 09/10/07 - 09/16/07 is 18% for Commercial over $250,000.

The monthly ceiling as prescribed by §303.005[3] for the period of 09/01/07 - 09/30/07 is 18% for Consumer/Agricultural/Commercial/credit through $250,000.

The monthly ceiling as prescribed by §303.005 for the period of 09/01/07 - 09/30/07 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.

[3]For variable rate commercial transactions only.

TRD-200704070
Leslie L. Pettijohn
Commissioner
Office of Consumer Credit Commissioner
Filed: September 4, 2007

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Texas Council for Developmental Disabilities

Intent to Award

The Texas Council for Developmental Disabilities announces its intent to award funds to the Baylor College of Medicine - Transition Medicine Clinic (TMC) project.

Background: The combined Medicine-Pediatric Residency program at Baylor College of Medicine responded to a TCDD Request for Proposals for unsolicited project proposals that would implement activities in the TCDD State Plan. This proposal was reviewed and approved for funding by the Council in their meeting August 3, 2007.

Description of Project: The Baylor Transition Medicine Clinic was established in January 2005 with the goal of delivering a medical home to the growing population of patients, ages 14 - 25, with disabilities and chronic illnesses and assisting them and their families as they transition from pediatric to adult-subspecialist services. It is believed to be the only program of its kind in Texas and perhaps the nation, and offers a medical home to patients with serious medical conditions. Baylor College of Medicine initiated the project with seed funding that will end in January 2008 and has seen a rise in the number of patients it serves. Therefore, the Clinic requested funding to maintain and expand its program while permanent funding is secured. TCDD believes this to be a promising practice innovation that is consistent with two objectives in the current TCDD State Plan.

Terms and Funding: Funding for this grant will end December 31, 2010. Funds awarded will not exceed $75,000 per year for up to three years.

For information regarding this announcement please contact Patrice A. LeBlanc, Grants Management Director (512) 437-5435 or email address: **Patrice.leblanc@tcdd.state.tx.us**.

TRD-200704081
Roger Webb
Executive Director
Texas Council for Developmental Disabilities
Filed: September 5, 2007

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Texas Commission on Environmental Quality

2007 Pollution Prevention Advisory Committee Request for Nominations

The Texas Commission on Environmental Quality (commission) is soliciting nominations to fill several positions on the Pollution Prevention Advisory Committee (PPAC). The legislatively created advisory committee, established under Texas Health and Safety Code, §361.0215, advises the commission on the state's policy and goals for pollution prevention and waste minimization.

The PPAC is composed of nine voting members who offer a balanced representation of environmental and public interest groups and the regulated community. The nine official members include: four members from an environmental or public interest organization; four members from the regulated community; and one member representing academia.

The commission may appoint *ex officio* members to provide additional participation from other members of the regulated community and the public who work on pollution prevention and performance-based regulatory initiatives. The commission currently has designated eight *ex officio* positions including one representative from each of the following sectors: small business, local government, agriculture, Department of Defense, labor, and the CLEAN TEXAS Program. The commission also extends *ex officio* positions to the chairs of the House Environmental Regulation Committee and the Senate Natural Resources Committee.

Individuals interested in being considered by the commission should submit a one-page letter of interest and brief resume or biography. **All materials must be received by the commission no later than 5:00 p.m. on October 5, 2007.**

The PPAC advises the commission on: the appropriate organization of state agencies and the financial and technical resources required to aid the state in its efforts to promote waste reduction and minimization; the development of public awareness programs to educate citizens about hazardous waste and the appropriate disposal of hazardous waste and hazardous materials that are used and collected by households; the provision of technical assistance to local governments for the development of waste management strategies designed to assist small quantity generators of hazardous waste; other possible programs to more effectively implement the state's hierarchy of preferred waste management technologies as set forth in Texas Health and Safety Code, §361.023(a); and the development of state purchasing guidelines for "environmentally preferable" products, under the authority provided in Texas Health and Safety Code, §361.423.

The PPAC operates under the requirements of 30 TAC Chapter 5, Advisory Committees and Groups. The PPAC meets a minimum of four times per year and as needed. Members may not miss three consecutive regularly scheduled meetings or more than half of all the regularly scheduled meetings in a one-year period. Semi-annual meetings typically last one full day and are typically held at the commission head-

quarters in Austin, Texas. The 79th Legislature, 2005, authorized reimbursement for committee members' travel expenses.

The commissioners invite nominations for these positions. Nominations may be made for oneself. Each nomination should include a brief cover letter and biographical summary that includes the individual's experience and qualifications, and an agreement to serve on the committee if appointed. Advisory committee members may serve two- or four-year terms, except as otherwise provided by law. Please submit nomination(s) for consideration by the commission for the following terms: **two full member representatives from the regulated community (to fill four-year terms that expire on August 31, 2011); two full member representatives from an environmental or public interest group (to fill four-year terms that expire on August 31, 2011); one *ex officio* representative from the agricultural community (to fill a four-year term that expires on August 31, 2011); one *ex officio* representative from a small business (to fill a four-year term that expires on August 31, 2011); and one *ex officio* representative from a city or county government (to fill a four-year term that expires on August 31, 2011).**

Written nominations must be received in the Small Business and Environmental Assistance Division Office **by 5:00 p.m. on October 5, 2007**, via mail, hand delivery, e-mail, or fax. Nominations should be directed to: Ted Hazen, Small Business and Environmental Assistance Division (MC 112), Texas Commission on Environmental Quality, P.O. Box 13087, Austin, Texas 78711-3087. They can also be sent via e-mail to *thazen@tceq.state.tx.us*, or they can be faxed to (512) 239-3165. Documents can be submitted via hand delivery to the Small Business and Environmental Assistance Division, 12100 Park 35 Circle, Building F, Suite 1301, Austin, Texas 78753.

Questions regarding the PPAC and the current nominations process can be directed to Ted Hazen at (512) 239-3100.

TRD-200704048
Robert Martinez
Director, Environmental Law Division
Texas Commission on Environmental Quality
Filed: August 31, 2007

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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 **October 15, 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 October 15, 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: ATC Leasing Company LLC; DOCKET NUMBER: 2007-0886-PST-E; IDENTIFIER: RN105224919; LOCATION: Denton, Denton County, Texas; TYPE OF FACILITY: trucking terminal with underground storage tank (UST); RULE VIOLATED: 30 Texas Administrative Code (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 §334.7(d)(3), by failing to notify the agency of any change or additional information regarding the USTs; and 30 TAC §334.48(a), by failing to prevent an unauthorized discharge of diesel fuel; PENALTY: $11,250; ENFORCEMENT COORDINATOR: Philip DeFrancesco, (817) 588-5800; REGIONAL OFFICE: 2301 Gravel Drive, Fort Worth, Texas 76118-6951, (817) 588-5800.

(2) COMPANY: Cemex Construction Materials, L.P.; DOCKET NUMBER: 2007-0825-AIR-E; IDENTIFIER: RN100219435; LOCATION: El Paso, El Paso County, Texas; TYPE OF FACILITY: rock crushing plant; RULE VIOLATED: 30 TAC §116.115(c), Air Permit Numbers 47915 and 48255, Special Condition Number 8, and Texas Health & Safety Code (THSC), §382.085(b), by failing to keep accurate records; PENALTY: $2,000; ENFORCEMENT COORDINATOR: Jessica Rhodes, (512) 239-2879; REGIONAL OFFICE: 401 East Franklin Avenue, Suite 560, El Paso, Texas 79901-1206, (915) 834-4949.

(3) COMPANY: Priten Y. Patel dba Easy Stop; DOCKET NUMBER: 2007-0776-PST-E; IDENTIFIER: RN102047313; LOCATION: Crosbyton, Crosby County, Texas; TYPE OF FACILITY: convenience store with retail sales of gasoline; RULE VIOLATED: 30 TAC §334.8(c)(4)(A)(vii) and (c)(5)(B)(ii), by failing to renew a delivery certificate by timely and proper submission of a completed UST registration and self-certification form; PENALTY: $900; ENFORCEMENT COORDINATOR: Judy Kluge, (817) 588-5800; REGIONAL OFFICE: 4630 50th Street, Suite 600, Lubbock, Texas 79414-3520, (806) 796-7092.

(4) COMPANY: Harris County Municipal Utility District No. 358; DOCKET NUMBER: 2007-0061-MWD-E; IDENTIFIER: RN102844776; LOCATION: Harris County, Texas; TYPE OF FACILITY: wastewater treatment; RULE VIOLATED: 30 TAC §305.125(1), Texas Pollutant Discharge Elimination System (TPDES) Permit Number 13296002, Interim II Effluent Limitations and Monitoring Requirements Number 1, and the Code, §26.121(a), by failing to comply with permitted limits for total copper; PENALTY: $2,900; ENFORCEMENT COORDINATOR: Catherine Albrecht, (713) 767-3500; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

(5) COMPANY: K&M Broussard Co.; DOCKET NUMBER: 2007-0808-MSW-E; IDENTIFIER: RN104859376; LOCATION: Beaumont, Jefferson County, Texas; TYPE OF FACILITY: general automotive maintenance; RULE VIOLATED: 30 TAC §324.6 and 40 Code of Federal Regulations §279.22(d), by failing to report and respond to releases of used oil; PENALTY: $262; ENFORCEMENT COORDINATOR: Clinton Sims, (512) 239-6933; REGIONAL OFFICE: 3870 Eastex Freeway, Beaumont, Texas 77703-1892, (409) 898-3838.

(6) COMPANY: Fred E. Kubitza Jr.; DOCKET NUMBER: 2007-1158-WOC-E; IDENTIFIER: RN103518668; LOCATION: Waco, McLennan County, Texas; TYPE OF FACILITY: public water supply; RULE VIOLATED: 30 TAC §30.5(a), by failing to obtain a required occupational license; PENALTY: $210; ENFORCEMENT COORDINATOR: Melissa Keller, (512) 239-1768; REGIONAL OFFICE: 6801 Sanger Avenue, Suite 2500, Waco, Texas 76710-7826, (254) 751-0335.

(7) COMPANY: Lindsey Contractors, Inc.; DOCKET NUMBER: 2007-1036-WQ-E; IDENTIFIER: RN105222772; LOCATION: Real County, Texas; TYPE OF FACILITY: road construction site; RULE VIOLATED: 30 TAC §327.5(a) and the Code, §26.121(a)(1), by failing to prevent the discharge of asphalt emulsion; and 30 TAC §327.3(b), by failing to provide notification to the commission of a reportable discharge or spill within 24 hours of discovery of the discharge; PENALTY: $6,000; ENFORCEMENT COORDINATOR: Michael Meyer, (512) 239-4492; REGIONAL OFFICE: 14250 Judson Road, San Antonio, Texas 78233-4480, (210) 490-3096.

(8) COMPANY: Rall Management Inc. dba Sunmart 435; DOCKET NUMBER: 2006-0943-PST-E; IDENTIFIER: RN102060092; LOCATION: Montgomery County, Texas; TYPE OF FACILITY: convenience store with retail sales of gasoline; RULE VIOLATED: 30 TAC §334.50(b)(1)(A), by failing to provide release detection; PENALTY: $1,750; ENFORCEMENT COORDINATOR: Melissa Keller, (512) 239-1768; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

(9) COMPANY: Tesco Industries, L.P.; DOCKET NUMBER: 2007-1003-AIR-E; IDENTIFIER: RN101908994; LOCATION: Bellville, Austin County, Texas; TYPE OF FACILITY: furniture manufacturing; RULE VIOLATED: 30 TAC §116.110(a) and THSC, §382.085(b) and §382.0518(a), by failing to obtain authorization to operate; PENALTY: $4,000; ENFORCEMENT COORDINATOR: Rebecca Johnson, (713) 767-3500; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

(10) COMPANY: West Harris County Municipal Utility District 4; DOCKET NUMBER: 2007-0565-MWD-E; IDENTIFIER: RN102821279; LOCATION: Harris County, Texas; TYPE OF FACILITY: wastewater treatment; RULE VIOLATED: 30 TAC §305.125(1) TPDES Permit Number 12119001, Final Effluent Limitations and Monitoring Requirement Numbers 1 and 2, and the Code, §26.121(a), by failing to comply with the permitted effluent limits; PENALTY: $5,080; ENFORCEMENT COORDINATOR: Deana Holland, (512) 239-2504; REGIONAL OFFICE: 5425 Polk Avenue, Suite H, Houston, Texas 77023-1486, (713) 767-3500.

TRD-200704079

Mary R. Risner

Director, Litigation Division

Texas Commission on Environmental Quality

Filed: September 5, 2007

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Notice of Comment Period and Announcement of Public Meeting on Proposed Air Quality Standard Permit for Sawmills

The Texas Commission on Environmental Quality (TCEQ) is providing an opportunity for public comment and will conduct a public meeting to receive testimony concerning the sawmill standard air permit proposed for issuance under the Texas Clean Air Act, Texas Health and Safety Code, §382.05195, Standard Permit, and 30 TAC Chapter 116, Subchapter F, Standard Permits.

PROPOSED STANDARD PERMIT

The proposed new air quality standard permit for sawmills would replace the current permit by rule (PBR) for sawmills available under 30 TAC §106.223, Saw Mills. The usefulness of the PBR as an authorization method is limited by the lack of lumber drying provisions. The proposed standard permit would authorize lumber drying using a variety of methods that have been evaluated for protection of public health. All other activities common to sawmills were also evaluated for their effect on air quality standards and potential for nuisance resulting in required internal setbacks for equipment and stockpiles from the sawmill property line. The proposed standard permit also contains fire prevention requirements. In a separate commission action, 30 TAC §106.223 will be repealed and will be unavailable for use upon issuance of this standard permit.

The New Source Review Program under 30 TAC Chapter 116, Control of Air Pollution by Permits for New Construction or Modification, requires any person who plans to construct any new facility or to engage in the modification of any existing facility which may emit air contaminants into the air of the state to obtain a permit in accordance with 30 TAC §116.111, General Application, satisfy the *de minimis* criteria of 30 TAC §116.119, De Minimis Facilities or Sources, or satisfy the conditions of a standard permit, a flexible permit, or a permit by rule before any actual work is begun on the facility. A standard permit authorizes the construction of new facilities or modification of existing facilities that are similar in terms of operations, processes, and emissions.

A standard permit is subject to the procedural requirements of 30 TAC §116.603, Public Participation in Issuance of Standard Permits, which includes a 30-day public comment period and a public meeting to provide an additional opportunity for public comment. Any person who may be affected by the emission of air pollutants from facilities that may be authorized under the standard permit is entitled to submit written or verbal comments regarding the proposed standard permit.

PUBLIC MEETING

A public meeting on the proposed standard permit for sawmills will be held in Austin, Texas. The meeting will be structured for the receipt of oral or written comments by interested persons. Individuals may present oral statements when called upon in order of registration. Open discussion with the audience will not occur during the meeting; however, TCEQ staff will be available to discuss the standard permit for sawmills 30 minutes prior to the meeting and staff will also answer questions after the meeting. The public meeting will be held on October 17, 2007 at 2:00 p.m. at the Texas Commission on Environmental Quality, Building C, Room 131E, 12100 Park 35 Circle, Austin.

PUBLIC COMMENT AND INFORMATION

Copies of the proposed standard permit for sawmills may be obtained from the TCEQ Web site at ***http://www.tceq.state.tx.us/permitting/air/nav/standard.html*** or by contacting the Texas Commission on Environmental Quality, Office of Permitting, Remediation, and Registration, Air Permits Division, at (512) 239-1250. Comments may be mailed to Beecher Cameron, Texas Commission on Environmental Quality, Office of Permitting, Remediation, and Registration, Air Permits Division, MC 163, P.O. Box 13087, Austin, Texas 78711-3087 or faxed to (512) 239-1070. All comments should reference the standard permit for sawmills. **Comments must be received by 5:00 p.m. on October 19, 2007.** To inquire about the submittal of comments or for further information, contact Mr. Cameron at (512) 239-1495. Si desea información en Español, puede llamar al (800) 687-4040.

Persons who have special communication or other accommodation needs who are planning to attend the public meeting should contact the TCEQ at (512) 239-1495. Requests should be made as far in advance as possible.

TRD-200704050
Robert Martinez
Director, Environmental Law Division
Texas Commission on Environmental Quality
Filed: August 31, 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 **October 15, 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) 2393400 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 October 15, 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: Donald Burkhardt dba Clearwood Recycling Center; DOCKET NUMBER: 2005-0959-MLM-E; TCEQ ID NUMBER: RN102952785; LOCATION: 9520 Easthaven Boulevard, Houston, Harris County, Texas; TYPE OF FACILITY: recycling facility; RULES VIOLATED: 30 TAC §328.5(c)(1), (f), and (g), by failing to make available for commission review a written cost estimate to show the cost of hiring a third party to close the facility by disposition of all processed and unprocessed materials in accordance with applicable regulations; 30 TAC §328.5(d), (f), and (g), by failing to make available for commission review records that show Mr. Burke established and maintained financial assurance for closure of the facility in accordance with 30 TAC Chapter 37, Subchapter J (relating to Financial Assurance for Recycling Facilities); 30 TAC §328.5(h), by failing to make available for commission review a copy of the facility's fire prevention and suppression plan to the local fire prevention authority having jurisdiction over the facility; 30 TAC §330.15(c), by failing to prevent the dumping of municipal solid waste without the written authorization of the commission; 30 TAC §324.6 and 40 Code of Federal Regulations Parts 264 and 265 and §279.22(a) and (c)(1), by failing to label or clearly mark containers containing used oil with the words "Used Oil"; and 30 TAC §324.4(1), by failing to prevent the discharge of disposal of used oil in a manner that endangers the public health or welfare of the environment; PENALTY: $6,774; STAFF ATTORNEY: Kari Gilbreth, Litigation Division, MC 175, (512) 239-1320; REGIONAL OFFICE: Houston Regional Office, 5425 Polk Street, Suite H, Houston, Texas 77023, (713) 767-3500.

TRD-200704054
Mary R. Risner
Director, Litigation Division
Texas Commission on Environmental Quality
Filed: August 31, 2007

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Notice of Water Quality Applications

The following notices were issued during the period of August 23, 2007 through August 30, 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, MC-105, P.O. Box 13087, Austin, Texas 78711-3087, WITHIN 30 DAYS OF THE DATE OF NEWSPAPER PUBLICATION OF THE NOTICE.

INFORMATION SECTION

CITY OF BARDWELL has applied for a renewal of TPDES Permit No. 13675-001, which authorizes the discharge of treated domestic wastewater at a daily average flow not to exceed 80,000 gallons per day. The facility is located approximately 1,500 feet northeast of the intersection of Farm-to-Market Road 984 and State Highway 34, approximately 1,000 feet northwest of State Highway 34 and Farm-to-Market Road 985, and 1/4 mile east of Bardwell city limits on the north side of State Highway 34 in Ellis County, Texas.

HARRIS COUNTY MUNICIPAL UTILITY DISTRICT NO. 180 has applied to for a renewal of TPDES Permit No. 12127-001 which authorizes the discharge of treated domestic wastewater at a daily average flow not to exceed 950,000 gallons per day. The facility is located at 5042 Innsbruk Drive, approximately 1/4 mile east of the intersection of Kleinsbrook Road and Bammel-North Houston Road in Harris County, Texas.

HARRIS COUNTY MUNICIPAL UTILITY DISTRICT NO. 278 has applied for a renewal of TPDES Permit No. WQ0014289001, which authorizes the discharge of treated domestic wastewater at a daily average flow not to exceed 375,000 gallons per day. The facility is located approximately 400 feet north of Will Clayton Parkway, and approximately 1.6 miles east of the intersection of Wilson Road and Will Clayton Parkway in Harris County, Texas.

INVERNESS FOREST IMPROVEMENT DISTRICT has applied for a renewal of TPDES Permit No. 10783-001, which authorizes the discharge of treated domestic wastewater at a daily average flow not to exceed 500,000 gallons per day. The facility is located on the north side of Cypress Creek, approximately 800 feet east of Hardy Road bridge crossing Cypress Creek in Harris County, Texas.

LAREDO WLE, LP which operates Laredo Power Station, has applied for a renewal of TPDES Permit No. WQ0001200000, which authorizes the discharge of cooling tower blowdown commingled with low volume waste, previously monitored chemical metal cleaning waste, and storm water runoff at a daily average flow not to exceed 1,300,000 gallons per day via Outfall 001, and chemical metal cleaning waste on an intermittent and flow variable basis via Outfall 101. The facility is located adjacent to the Rio Grande, west of the intersection of Interstate Highway 35 and Del Mar Boulevard in the City of Laredo, Webb County, Texas.

NORTH MISSION GLEN MUNICIPAL UTILITY DISTRICT has applied to the Texas Commission on Environmental Quality (TCEQ) for a renewal of TPDES Permit No. WQ0012379001, which authorizes the discharge of treated domestic wastewater at an annual average flow not to exceed 1,180,000 gallons per day. The facility is located approximately 1/2 mile west of Gaines Road and approximately 3/4 mile south of the intersection of Addicks-Clodine Road and Beechnut street in Fort Bend County, Texas.

NRG TEXAS POWER LLC which operates the T.H. Wharton Electric Generating Station, a steam electric station, has applied for a renewal of TPDES Permit No. WQ0001039000, which authorizes the discharge of: cooling tower blowdown, storm water, flush water, and previously monitored effluents (PME from Outfalls 101, 201, 301 and 401 at a daily average flow not to exceed 3.95 million gallons per day via Outfall 001, low volume wastewater on an intermittent and flow variable basis via internal Outfall 101, metal cleaning wastewater on an intermittent and flow variable basis via internal Outfall 201; low volume wastewater, storm water, and spill prevention and control coutermeasures (SPCC) sources on an intermittent and flow variable basis via internal Outfall 301; and treated domestic wastewater on a flow variable basis via internal Outfall 401. The facility is located at 16301 State Highway 249, approximately 1000 feet south of the intersection of Mills Road and State Highway 249 in the City of Houston, Harris County, Texas.

CITY OF POINT has applied for a renewal of TPDES Permit No. 14470-001, which authorizes the discharge of treated filter backwash water at a daily average flow not to exceed 48,000 gallons per day. The facility is located one mile west of the intersection of Farm-to-Market Road 47 and County Road 1470, on the north side of County Road 1470 in Rains County, Texas.

TEXAS DEPARTMENT OF TRANSPORTATION has applied for a new permit, proposed Texas Pollutant Discharge Elimination System (TPDES) Permit No. WQ0014790001, to authorize the discharge of treated domestic wastewater at a daily average flow not to exceed 11,000 gallons per day. The facility was previously permitted under TPDES Permit No. 12951-001 which expired September 1, 2006. The facility is located on the northbound Right-of-Way of Interstate Highway 35W, approximately 0.8 mile north of the intersection of Interstate Highway 35W and Farm-to-Market Road 917 in Johnson County, Texas.

THE TEXAS DEPARTMENT OF TRANSPORTATION has applied to the TCEQ for a new permit to authorize the discharge of treated domestic wastewater at a daily average flow not to exceed 15,000 gallons per day. This facility was previously authorized under permit No. 11643-001 which expired February 1, 2007. The facility is located along the southbound lane of U.S. Highway 59 approximately 1.5 miles north of the intersection of U.S. Highway 59 and Farm-to-Market Road 942 in Polk County, Texas.

WESTSIDE WATER, LLC has applied to the Texas Commission on Environmental Quality (TCEQ) for a major amendment to TPDES Permit No. 14434-001 to authorize an increase in the discharge of treated domestic wastewater from a daily average flow not to exceed 120,000 gallons per day to a daily average flow not to exceed 240,000 gallons per day. The facility is located at 21118 West Farwood Terrace, Cypress (2.1 miles northeast of the intersection of Bauer Road and U.S. 290 and approximately 2,000 feet north of Schiel Road) in Harris County, Texas.

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-200704083
LaDonna Castañuela
Chief Clerk
Texas Commission on Environmental Quality
Filed: September 5, 2007

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Notice of Water Rights Applications

Notices issued August 29, 2007.

APPLICATION NO 12206; Jefferson County Drainage District, No. 6, P.O. Box 20078, Beaumont, Texas 77720-0078, Applicant, has applied for a Water Use Permit to construct and maintain multiple fixed crest weirs and one flap-gate outlet structure and to divert flood flows from the South Fork Taylors Bayou, Neches-Trinity Coastal Basin, into an excavated diversion channel for storage and discharge into the Gulf Intercoastal Waterway for flood control purposes in Jefferson County. The application and fees were received on May 11, 2007, and additional information and fees were received on July 9, 2007. The application was declared administratively complete and accepted for filing with the Office of the Chief Clerk on July 18, 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. 5889A; TXU Mining Company L.P. 1601 Bryan Street, Dallas, TX 75201-3411, Applicant, has applied for an amendment to Water Use Permit 5889 to maintain an additional existing reservoir known as AIV-4 on an unnamed tributary of Martin Creek for mining purposes and to divert and use 250 acre-feet of water per year on a term basis from three reservoirs being the two currently authorized (AI-50R and AI-129R) and the additional reservoir (AIV-4) on unnamed tributaries of Martin Creek, tributary of the Sabine River, Sabine River Basin for mining purposes in Panola and Rusk Counties. The application and partial fees were received on April 26, 2007. Additional information and fees were received on June 25, 2007. The application was accepted for filing and declared administratively complete on July 13, 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, TCEQ, 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-200704084

LaDonna Castañuela

Chief Clerk

Texas Commission on Environmental Quality

Filed: September 5, 2007

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Texas Health and Human Services Commission

Correction of Error

The Texas Health and Human Services Commission submitted a public notice concerning Amendment 765, Transmittal Number TX 07-066 for publication in the August 17, 2007, issue of the *Texas Register* (32 TexReg 5212). The document was docketed as TRD-200703410 and appeared in the "In Addition" portion of the issue. Due to a Texas Register mistake, a typographical error appears in the first line of the notice on page 5212, second column. The number "07-0066" should be "07-066". The first line of the notice should read as follows:

"The Texas Health and Human Services Commission announces its intent to submit Amendment 765, Transmittal Number TX 07-066. . . ."

TRD-200704093

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Notice of Public Hearing on Proposed Medicaid Payment Rates

Hearing. The Texas Health and Human Services Commission (HHSC) will conduct a public hearing on October 1, 2007, at 1:00 p.m. to receive public comment on the proposed Medicaid payment rates for procedure codes relating to physician-administered drugs and contraceptives. These additions to the Texas Medicaid program are at the request of the Office of the Medical Director (OMD). The public hearing will be held in the Lone Star Conference Room of the Texas Health and Human Services Commission, Braker Center, Building H, located at 11209 Metric Boulevard, Austin, Texas. Entry is through Security at the main entrance of the building, which faces Metric Boulevard. The hearing will be held in compliance with Human Resources Code §32.0282 and 1 Texas Administrative Code (TAC) §355.201(e) - (f), which require public notice and hearings on proposed Medicaid reimbursements. Persons requiring Americans with Disability Act (ADA) accommodation or auxiliary aids or services should contact Kimbra Rawlings by calling (512) 491-1174, at least 72 hours prior to the hearing so appropriate arrangements can be made.

Proposal. The proposed payment rates will be effective November 28, 2007. The proposed payment rates for the physician-administered drugs and contraceptives procedure codes are as follows:

Procedure Codes and Proposed Payment Rates

Type of Service (TOS)	Procedure Code	Current Medicaid Fee	Proposed Medicaid Fee
1	1-J7303	$0.00	$37.32
1	1-J7304	$0.00	$15.36

Type of Service (TOS) code key: 1-Medical Services

Methodology and Justification. The proposed payment rates are calculated in accordance with 1 TAC §355.8085, which addresses the reimbursement methodology for physicians and certain other practitioners; and the specific fee guidelines published in Section 2.2.1.2 of the 2007 Texas Medicaid Provider Procedures Manual. 1 TAC §355.8085 requires HHSC to review the fees for individual services at least every two years.

Briefing Package. A briefing package describing the proposed payment rates will be available on or after September 17, 2007. Interested parties may obtain a copy of the briefing package prior to the hearing by contacting Kimbra Rawlings by telephone at (512) 491-1174; by fax at (512) 491-1998; or by e-mail at Kimbra.Rawlings@hhsc.state.tx.us. The briefing package also will be available at the public hearing.

Written Comments. Written comments regarding the proposed payment rates may be submitted in lieu of, or in addition to, oral testimony until 5:00 p.m. the day of the hearing. Written comments may be sent by U.S. mail to the attention of Kimbra Rawlings, Texas Health and Human Services Commission, Rate Analysis, Mail Code H-400, P.O. Box 85200, Austin, Texas 78708-5200; by fax to Kimbra Rawlings at (512) 491-1998; or by e-mail to Kimbra.Rawlings@hhsc.state.tx.us. In addition, written comments may be sent by overnight mail or hand delivered to Kimbra Rawlings, HHSC, Rate Analysis, Mail Code H-400, Braker Center, Building H, 11209 Metric Boulevard, Austin, Texas 78758-4021.

** Required Notice: The five character codes included in this notice are obtained from the Current Procedural Terminology (CPT®), copyright 2006 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physicians. The responsibility for the content of*

this notice is with HHSC and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in this notice. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of this notice should refer to the most recent Current Procedural Terminology, which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply. CPT is a registered trademark of the American Medical Association.

TRD-200704091
Steve Aragón
Chief Counsel
Texas Health and Human Services Commission
Filed: September 5, 2007

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Texas Department of Insurance

Company Licensing

Application for admission to the State of Texas by ZURICH COMPANIA DE SEGUROS, S.A., a foreign fire and/or casualty company. The home office is in Lomas de Chapultepec, 1100 Mexico, D.F.

Application to change the name of INDUSTRIAL-ALLIANCE PACIFIC LIFE INSURANCE COMPANY to INDUSTRIAL ALLIANCE PACIFIC INSURANCE AND FINANCIAL SERVICES INC., a foreign life, accident and/or health company. The home office is in Vancouver, Canada.

Any objections must be filed with the Texas Department of Insurance, within twenty (20) calendar days from the date of the *Texas Register* publication, addressed to the attention of Godwin Ohaechesi, 333 Guadalupe Street, M/C 305-2C, Austin, Texas 78701.

TRD-200704082
Gene C. Jarmon
Chief Clerk and General Counsel
Texas Department of Insurance
Filed: September 5, 2007

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Texas Lottery Commission

Instant Game Number 1001 "X's & O's"

1.0 Name and Style of Game.

A. The name of Instant Game No. 1001 is "X'S & O'S". The play style is "row/column/diagonal".

1.1 Price of Instant Ticket.

A. Tickets for Instant Game No. 1001 shall be $3.00 per ticket.

1.2 Definitions in Instant Game No. 1001.

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: X SYMBOL and O 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. 1001 - 1.2D

PLAY SYMBOL	CAPTION
X SYMBOL	
O SYMBOL	

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. 1001 - 1.2E

CODE	PRIZE
THR	$3.00
SIX	$6.00
NIN	$9.00
TWL	$12.00
EHT	$18.00
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 $3.00, $6.00, $9.00, $12.00, $18.00 or $20.00.

H. Mid-Tier Prize - A prize of $40.00, $100 or $500.

I. High-Tier Prize - A prize of $1,000 or $30,000.

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 (1001), a seven (7) digit pack number, and a three (3) digit ticket number. Ticket numbers start with 001 and end with 125 within each pack. The format will be: 1001-0000001-001.

L. Pack - A pack of "X'S & O'S" Instant Game tickets contains 125 tickets, packed in plastic shrink-wrapping and fanfolded in pages of one (1). There will be 2 fanfold configurations for this game. Configuration A will show the front of ticket 001 and the back of ticket 125. Configuration B will show the back of ticket 001 and the front of ticket 125.

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 "X'S & O'S" Instant Game No. 1001 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 "X'S & O'S" Instant Game is determined once the latex on the ticket is scratched off to expose 18 (eighteen) Play Symbols. If a player reveals 3 (three) X's or 3 (three) O's in any one row, column or diagonal line, the player wins the corresponding prize. Each game plays separately. 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 18 (eighteen) 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 18 (eighteen) 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 18 (eighteen) Play Symbols must be exactly one of those described in Section 1.2.C of these Game Procedures;

17. Each of the 18 (eighteen) 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 un-

played 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. Adjacent tickets within a pack will not have identical patterns. Two tickets have identical patterns when they have the same symbols in the same positions.

B. There will be a random distribution of all symbols on the ticket unless affected by other constraints, play action or prize structure.

C. All games on the ticket will be unique. Identical games are defined as two games having the same symbols in the same positions.

D. Each game will have either four (4) X's and five (5) O's, or five (5) X's and four (4) O's, except when required by the prize structure.

E. In each game, play symbols will be used evenly to form winning matches, unless affected by other constraints in this document.

F. In each game, winning patterns will be distributed randomly, except as required by prize structure and other constraints. A pattern is the complete Tic Tac Toe grid, example: XXXXOOOXO.

2.3 Procedure for Claiming Prizes.

A. To claim a "X'S & O'S" Instant Game prize of $3.00, $6.00, $9.00, $12.00, $18.00, $20.00, $40.00, $100, 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 $40.00, $100 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 "X'S & O'S" Instant Game prize of $1,000 or $30,000, 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 "X'S & O'S" 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;

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 "X'S & O'S" 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 "X'S & O'S" 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 5,040,000 tickets in the Instant Game No. 1001. The approximate number and value of prizes in the game are as follows:

Figure 3: GAME NO. 1001 - 4.0

Prize Amount	Approximate Number of Winners*	Approximate Odds are 1 in**
$3	645,120	7.81
$6	403,200	12.50
$9	60,480	83.33
$12	90,720	55.56
$18	40,320	125.00
$20	20,160	250.00
$40	20,160	250.00
$100	5,166	975.61
$500	2,310	2,181.82
$1,000	84	60,000.00
$30,000	10	504,000.00

*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 3.91. 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. 1001 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. 1001, 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-200704063
Kimberly L. Kiplin
General Counsel
Texas Lottery Commission
Filed: September 4, 2007

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Instant Game Number 1014 "Stocking Stuffer"

1.0 Name and Style of Game.

A. The name of Instant Game No. 1014 is "STOCKING STUFFER". The play style is "match 3 of 9 with auto win".

1.1 Price of Instant Ticket.

A. Tickets for Instant Game No. 1014 shall be $1.00 per ticket.

1.2 Definitions in Instant Game No. 1014.

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: $1.00, $2.00, $4.00, $5.00, $10.00, $20.00, $40.00, $50.00, $100, $1,000 and STAR 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. 1014 - 1.2D

PLAY SYMBOL	CAPTION
$1.00	ONE$
$2.00	TWO$
$4.00	FOUR$
$5.00	FIVE$
$10.00	TEN$
$20.00	TWENTY
$40.00	FORTY
$50.00	FIFTY
$100	ONE HUND
$1,000	ONE THOU
STAR SYMBOL	AUTO

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. 1014 - 1.2E

CODE	PRIZE
ONE	$1.00
TWO	$2.00
FOR	$4.00
FIV	$5.00
TEN	$10.00
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 $1.00, $2.00, $4.00, $5.00, $10.00 or $20.00.

H. Mid-Tier Prize - A prize of $40.00, $50.00 or $100.

I. High-Tier Prize - A prize of $1,000.

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 (1014), a seven (7) digit pack number, and a three (3) digit ticket number. Ticket numbers start with 001 and end with 150 within each pack. The format will be: 1014-0000001-001.

L. Pack - A pack of "STOCKING STUFFER" Instant Game tickets contains 150 tickets, packed in plastic shrink-wrapping and fanfolded in pages of five (5). Tickets 001 to 005 will be on the top page; tickets 006 to 010 on the next page; etc.; and tickets 146 to 150 will be on the last page with backs exposed. Ticket 001 will be folded over so the front of ticket 001 and 010 will 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 "STOCKING STUFFER" Instant Game No. 1014 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 "STOCKING STUFFER" Instant Game is determined once the latex on the ticket is scratched off to expose 9 (nine) Play Symbols. If a player reveals 3 matching dollar amounts, the player wins that dollar amount. If a player reveals 2 matching dollar amounts and a STAR play symbol, the player wins that dollar amount instantly! 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 9 (nine) 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 9 (nine) 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 9 (nine) Play Symbols must be exactly one of those described in Section 1.2.C of these Game Procedures.

17. Each of the 9 (nine) 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 four or more matching play symbols.

C. No three or more pairs of play symbols.

D. When the "star" (auto win) play symbol appears, there will only be one pair of matching play symbols on the ticket.

E. The top prize will appear on every ticket.

2.3 Procedure for Claiming Prizes.

A. To claim a "STOCKING STUFFER" Instant Game prize of $1.00, $2.00, $4.00, $5.00, $10.00, $20.00, $40.00, $50.00 or $100, 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 $40.00, $50.00 or $100 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 "STOCKING STUFFER" Instant Game prize of $1,000, 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 "STOCKING STUFFER" 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 "STOCKING STUFFER" 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 "STOCKING STUFFER" 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 13,200,000 tickets in the Instant Game No. 1014. The approximate number and value of prizes in the game are as follows:

Figure 3: GAME NO. 1014 - 4.0

Prize Amount	Approximate Number of Winners*	Approximate Odds are 1 in**
$1	2,112,000	6.25
$2	616,000	21.43
$4	264,000	50.00
$5	132,000	100.00
$10	88,000	150.00
$20	22,000	600.00
$40	16,500	800.00
$50	7,150	1,846.15
$100	4,125	3,200.00
$1,000	110	120,000.00

*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 4.05. 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. 1014 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. 1014, 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-200704064
Kimberly L. Kiplin
General Counsel
Texas Lottery Commission
Filed: September 4, 2007

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Public Utility Commission of Texas

Announcement of Application for an Amendment to a State-Issued Certificate of Franchise Authority

The Public Utility Commission of Texas (commission) received an application on August 28, 2007, for an amendment to a state-issued certificate of franchise authority (CFA), pursuant to §§66.001 - 66.016 of the Public Utility Regulatory Act (PURA).

Project Title and Number: Application of Marcus Cable Associates, LLC, d/b/a Charter Communications, for an Amendment to a State-Issued Certificate of Franchise Authority, Project Number 34678 before the Public Utility Commission of Texas.

Information on the application may be obtained by contacting 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. 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 inquiries should reference Project Number 34678.

TRD-200704071
Adriana A. Gonzales
Rules Coordinator
Public Utility Commission of Texas
Filed: September 4, 2007

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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 August 30, 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 ESCO1, LLC for Retail Electric Provider (REP) Certification, Docket Number 34689 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 September 21, 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 34689.

TRD-200704076

Adriana A. Gonzales
Rules Coordinator
Public Utility Commission of Texas
Filed: September 4, 2007

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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 August 30, 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 TexRep2, LLC for Retail Electric Provider (REP) Certification, Docket Number 34690 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 September 21, 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 34690.

TRD-200704077
Adriana A. Gonzales
Rules Coordinator
Public Utility Commission of Texas
Filed: September 4, 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 August 30, 2007, with the Public Utility Commission of Texas (commission) for an amendment to a certificated service area boundary in Collin County, Texas.

Docket Style and Number: Application of AT&T Texas to Amend Certificate of Convenience and Necessity between the McKinney and Anna Exchanges, Docket Number 34694.

The Application: The minor boundary amendment is being filed to realign the service boundaries of the McKinney and Anna exchanges of AT&T Texas.

Persons wishing to comment on the action sought or intervene should contact the Public Utility Commission of Texas by September 21, 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 34694.

TRD-200704074
Adriana A. Gonzales
Rules Coordinator
Public Utility Commission of Texas
Filed: September 4, 2007

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Notice of Application for Sale, Transfer, or Merger

Notice is given to the public of a joint application for sale, transfer, or merger filed with the Public Utility Commission of Texas (commission) on August 30, 2007, pursuant to the Public Utility Regulatory Act, Texas Utilities Code Annotated §§14.101, 36.001, and 37.154 (Vernon 2007) (PURA).

Docket Style and Number: Joint Application of LCRA Transmission Services Corporation and AEP Texas Central Company to Transfer Certificate Rights and for Approval of Transfer of Facilities, Docket Number 34684.

The Application: This transaction involves the transfer from AEP Texas Central Company to LCRA Transmission Services Corporation (collectively, Applicants) certain AEP Texas Central-owned 69-kv transmission lines and related facilities and associated certificate of convenience and necessity (CCN) rights. The transmission lines, the total length of which is approximately 273 miles, are located in Caldwell, Guadalupe, Gonzales, Karnes, Dewitt, Colorado, and Wharton Counties. They are being transferred at their net book value, which was approximately $3 million as of March 2007 and will be updated when the transaction closes after regulatory approvals have been obtained. The facilities proposed for transfer from AEP Texas Central to LCRA TSC comprise the following: (a) the Glidden to El Campo Loop; and (b) the Luling to Kenedy Loop.

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 34684.

TRD-200704073
Adriana A. Gonzales
Rules Coordinator
Public Utility Commission of Texas
Filed: September 4, 2007

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Notice of Application for Waiver

Notice is given to the public of the filing with the Public Utility Commission of Texas of an application on August 28, 2007 for waiver from the filing requirements in Project Number 34515 and a permanent waiver from the requirements of P.U.C. Substantive Rule §22.223(g).

Docket Title and Number: Application of Panhandle Telephone Cooperative, Inc. for Exemption from Project Number 34515 and P.U.C. Substantive Rule §26.22(g); Docket Number 34679.

Persons who wish 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. 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 34679.

TRD-200704072
Adriana A. Gonzales
Rules Coordinator
Public Utility Commission of Texas
Filed: September 4, 2007

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Texas Department of Transportation

Aviation Division - Request for Proposal for Aviation Engineering Services

The City of Coleman, 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:

The following is a listing of proposed projects at the Coleman Municipal Airport during the course of the next five years through multiple grants.

Current Project: TxDOT CSJ No. 0823COLMN. Scope: Provide engineering/design services to rehabilitate and mark Runway 15-33, rehabilitate hangar access taxiway, rehabilitate and mark stub taxiway, rehabilitate and mark taxiway to Runway 33 end, rehabilitate and mark apron, rehabilitate and mark taxiway to Runway 15 end, install game fencing at the Coleman Municipal Airport.

The **DBE** goal is set at 6%. TxDOT Project Manager is Clayton Bridwell.

Future scope work items for engineering/design services within the next five years may include but are not necessarily limited to the following:

1. Expand terminal apron

The City of Coleman reserves the right to determine which of the above scope of services may or may not be awarded to the successful firm and to initiate additional procurement action for any of the services above.

To assist in your proposal preparation the criteria, 5010 drawing and most recent airport layout plan are available online at **www.dot.state.tx.us/avn/avninfo/notice/consult/index.htm** by selecting Coleman Municipal Airport. The proposal should address a technical approach for the current scope. 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 **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 a PDF Template.

Please note:

Five 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 October 9, 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 Sheri Quinlan.

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 Sheri Quinlan, Grant Manager at 1-800-68-PILOT at extension 4517. For technical questions, please contact Clayton Bridwell, at 1-800-68-PILOT at extension 4531.

TRD-200704000
Joanne Wright
Deputy General Counsel
Texas Department of Transportation
Filed: August 30, 2007

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Aviation Division - Request for Proposal for Aviation Engineering Services

The City of Brady, 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:

The following is a listing of proposed projects at the Curtis Field Municipal Airport during the course of the next five years through multiple grants.

Current Project: TxDOT CSJ No. 0823BRADY. Scope: Provide engineering/design services to reconstruct outer Runway 17-35 edges, rehabilitate and mark adjacent runway pavement, regrade/compost runway and taxiway shoulders, crack seal Runway 17-35, and parallel taxiway at the Curtis Field Municipal Airport.

The **DBE** goal is set at 5%. TxDOT Project Manager is Harry Lorton, P.E.

Future scope work items for engineering/design services within the next five years may include but are not necessarily limited to the following:

1. Rehabilitate Ag apron
2. Rehabilitate and mark partial taxiway
3. Rehabilitate/overlay Runway 17-35
4. Rehabilitate hangar access taxiway
5. Rehabilitate stub taxiway at intersection of Runway 17-35 and Runway 8-26
6. Mark Runway 17-35
7. Rehabilitate apron
8. Construct turnaround Runway 35

9. Install lighting for existing helicopter pads

10. Extend runway and parallel taxiway

The City of Brady reserves the right to determine which of the above scope of services may or may not be awarded to the successful firm and to initiate additional procurement action for any of the services above.

To assist in your proposal preparation the criteria, 5010 drawing, and most recent airport layout plan are available online at **www.dot.state.tx.us/avn/avninfo/notice/consult/index.htm** by selecting Brady/Curtis Field Airport. The proposal should address a technical approach for the current scope. 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 **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 a PDF Template.

Please note:

Six 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 October 9, 2007 at 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 Sheri Quinlan.

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 Sheri Quinlan, Grant Manager at 1-800-68-PILOT at extension 4517. For technical questions, please contact Harry Lorton, P.E., at 1-800-68-PILOT at extension 4535.

TRD-200704001

Joanne Wright

Deputy General Counsel

Texas Department of Transportation

Filed: August 30, 2007

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Aviation Division - Request for Proposal for Aviation Engineering Services

The City of Bonham, 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:

The following is a listing of proposed projects at Jones Field Airport, Bonham, Texas during the course of the next five years through multiple grants.

Current Project: TxDOT CSJ No. 08001BONHM. Scope: Provide engineering/design services for design, construction, and marking of a partial parallel taxiway.

The DBE goal is set at **11%**. TxDOT Project Manager is Charles Graham.

Future scope work items for engineering/design services within the next five years may include but are not necessarily limited to the following:

1. Rehabilitate turnarounds

2. Rehabilitate and mark Runway 17-35

3. Rehabilitate apron

4. Construct and mark partial parallel taxiway

5. Overlay stub taxiway

6. Rehabilitate hangar access taxiways

7. Rehabilitate entrance road

8. Expand apron

9. Install taxiway reflectors

10. Construct auto parking (10 spaces)

The City of Bonham reserves the right to determine which of the above scope of services may or may not be awarded to the successful firm and to initiate additional procurement action for any of the services above.

To assist in your proposal preparation the most recent Airport Layout Plan, 5010 drawing, and sponsor's criteria are available online at **www.dot.state.tx.us/avn/avninfo/notice/consult/index.htm** by selecting Jones Field Airport. The proposal should address a technical approach for the current scope. 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 **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 Tx-

DOT website as addressed above. Utilization of Form AVN-550 from a previous download may not be the exact same format. Form AVN-550 is a PDF 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 October 5, 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 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, phone 1-800-68-PILOT, extension 4518. For technical questions, please contact Charles Graham, Project Manager, at 1-800-68-PILOT, extension 4549.

TRD-200704088
Joanne Wright
Deputy General Counsel
Texas Department of Transportation
Filed: September 5, 2007

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Aviation Division - Request for Proposal for Aviation Engineering Services

The City of Gainesville, 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:

The following is a listing of proposed projects at Gainesville Municipal Airport during the course of the next five years through multiple grants.

Current Project: TxDOT CSJ No. 0803GAINS. Scope: Provide engineering/design services for design and construction of a hangar access taxiway.

The **DBE** goal is set at **10%**. TxDOT Project Manager is Charles Graham.

Future scope work items for engineering/design services within the next five years may include but are not necessarily limited to the following:

1. Rehabilitate concrete terminal apron
2. Rehabilitate Taxiways B and filet
3. Rehabilitate Taxiway C
4. Rehabilitate Taxiway E
5. Rehabilitate and mark Runway 17-35
6. Rehabilitate and mark Runway 12-30
7. Rehabilitate Taxiway A and holding area
8. Rehabilitate Taxiway D and stub

The City of Gainesville reserves the right to determine which of the above scope of services may or may not be awarded to the successful firm and to initiate additional procurement action for any of the services above.

To assist in your proposal preparation the most recent Airport Layout Plan, 5010 drawing, and sponsor's criteria are available online at **www.dot.state.tx.us/avn/avninfo/notice/consult/index.htm** by selecting Gainesville Municipal Airport. The proposal should address a technical approach for the current scope. 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 **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 a PDF 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 October 5, 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 Edie Stimach.

The consultant selection committee will be composed of Aviation Division staff 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, phone 1-800-68-PILOT, extension 4518. For technical questions, please contact Charles Graham, Project Manager, at 1-800-68-PILOT, extension 4549.

TRD-200704090
Joanne Wright
Deputy General Counsel
Texas Department of Transportation
Filed: September 5, 2007

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Aviation Division - Request for Proposal for Professional Services

The City of Caddo Mills, through its agent the Texas Department of Transportation (TxDOT), intends to engage an aviation professional services firm for services pursuant to Government Code, Chapter 2254, Subchapter A. TxDOT Aviation Division will solicit and receive proposals for professional services as described below:

Airport Sponsor: The City of Caddo Mills, Caddo Mills Municipal Airport. TxDOT CSJ No. 0801CADDO. Scope: Prepare an Airport Development Plan which includes, but is not limited to, information regarding existing and future conditions, proposed facility development to meet existing and future demand, constraints to develop, anticipated capital needs, financial considerations, management structure and options, as well as an updated Airport Layout Plan. The Airport Development Plan should be tailored to the individual needs of the airport.

The HUB goal is race neutral. TxDOT Project Manager is Sandra Braden.

Interested firms shall utilize the Form AVN-551, titled "Aviation Planning 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, URL address **http://www.dot.state.tx.us/avn/avn551.doc**. 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-551, firms are encouraged to download Form AVN-551 from the TxDOT website as addressed above. Utilization of Form AVN-551 from a previous download may not be the exact same format. Form AVN-551 is an MS Word Template.

Please note:

Eight completed, unfolded copies of Form AVN-551 **must be received** by TxDOT Aviation at 150 East Riverside Drive, 5th Floor, South Tower, Austin, Texas 78704 no later than October 9, 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 Sheri Quinlan.

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. Below is the criterion for evaluating planning proposals. 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 Sheri Quinlan, Grant Manager, or Sandra Braden, Project Manager for technical questions at 1-800-68-PILOT (74568).

TRD-200704089
Joanne Wright
Deputy General Counsel
Texas Department of Transportation
Filed: September 5, 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).