

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 4. AGRICULTURE

PART 2. TEXAS ANIMAL HEALTH COMMISSION

CHAPTER 41. FEVER TICKS

4 TAC §41.1, §41.8

The Texas Animal Health Commission (commission) proposes amendments to §41.1, concerning Definition of Terms, and a new §41.8, concerning Dipping, Treatment, and Vaccination of Animals, in Chapter 41, which is entitled "Fever Ticks."

Elsewhere in this issue of the *Texas Register*, the commission contemporaneously proposes the repeal of the existing §41.8, concerning Dipping and Treatment of Livestock.

The purpose of the amendments to §41.1 is to add a fever tick vaccine definition. The purpose of a new §41.8 is to add fever tick vaccine requirements for beef cattle located in a control purpose quarantine area, temporary preventative quarantine area or tick eradication quarantine area, and other beef cattle or premises epidemiologically determined by the commission to be at an increased risk for fever ticks. A new §41.8 will also clarify and better organize the different requirements for dipping, treatment, and vaccination. The title of §41.8 is being changed to accurately capture that the requirements apply to animals, not just livestock, capable of hosting or transporting ticks capable of carrying *Babesia*, and to add vaccination to the title.

The purpose of the Texas Cattle Fever Tick Eradication Program is to eradicate fever ticks through the management of a permanent quarantine zone, as well as through temporary quarantine areas, created to address the presence of ticks outside the permanent zone.

The USDA Cattle Fever Tick Eradication Program, USDA Agriculture Research Service, and the commission have developed a vaccine for the purpose of acting as a preventative to be used against fever ticks. Collaboratively, they worked with a major pharmaceutical company for five years to get the vaccine through the approval process by USDA Center for Veterinary Biologics (CVB) approval process with the intent for the fever tick vaccine to be integrated into the eradication program.

The fever tick vaccine was developed and manufactured by a major pharmaceutical company with extensive experience in livestock products. It is a recombinant product which has no live, modified live, nor killed bacterial or viral components. It is derived from epithelial lining of the fever tick gut. Cattle vaccinated with this antigen produce an antibody response at high levels in blood. Fever ticks which feed on immunized cattle consume high levels of the antibody in blood meal. The antigen-antibody response occurs in the stomach of the tick and

effectively destroys the gut lining of the tick, reducing the tick's capabilities to produce offspring and potentially killing the tick.

The fever tick vaccine requires two priming doses 28 days apart. The maximum protection requires boosters every 6 months. This is administered by intramuscular injection in the neck region of cattle. The vaccine is approved for use in beef cattle two months of age and older. There is insufficient safety data for use of the vaccine in dairy cattle and, as such, the vaccine is not authorized for use in dairy cattle at this time. The USDA CVB requires a slaughter withholding period of 60 days following administration of the vaccine and that is provided for in the proposal.

There are numerous benefits of the fever tick vaccination, with the most significant being the potential to eradicate ticks from infested premises. The vaccine provides long term protection against re-infestation; after the initial inoculations cattle only need, at most, two inoculations per year and premises are protected continuously because cattle are fever tick immune. In this regard, the vaccine substantially prevents re-establishment of ticks when new incursions occur from stray livestock and wildlife from Mexico in US premises stocked with immunized cattle. The vaccine is simple to administer and works synergistically with treatment to promote more efficient elimination of fever ticks on premises with less dependency on chemical and systemic acaricides.

It is also noted that although the vaccine is over 95% effective against *Rhipicephalus (Boophilus) annulatus*, it is only 70% effective against *Rhipicephalus (Boophilus) microplus* but, the booster effect over a 2-3 year period is believed to raise efficacy to near 90% for *Rhipicephalus (Boophilus) microplus*. The next generation vaccine, expected in two years, is predicted to have high efficacy for both strains of fever ticks with fewer annual boosters.

FISCAL NOTE

Ms. Larissa Schmidt, Director of Administration, Texas Animal Health Commission, has determined for the first five-year period the rules are in effect, there will be no significant additional fiscal implications for state or local government as a result of enforcing or administering the rules. An Economic Impact Statement (EIS) is required if the proposed rule has an adverse economic effect on small businesses. The agency has evaluated the requirements and determined that there is not an adverse economic impact and, therefore, there is no need to do an EIS. It is being applied to everyone restricted by a fever tick quarantine because the cattle have to be inspected for fever ticks, which provides an opportunity to have the cattle vaccinated at that time. Furthermore, having the cattle vaccinated will act as a preventative for fever ticks, which will help control and eventually eradicate fever ticks from infested premises.

PUBLIC BENEFIT NOTE

Ms. Schmidt has also determined that for each year of the first five years the rules are in effect, the public benefit anticipated as a result of enforcing the rules will be to have a preventative measure in place to control and eradicate fever ticks from a herd or premises.

LOCAL EMPLOYMENT IMPACT STATEMENT

In accordance with Texas Government Code §2001.022, this agency has determined that the proposed rules will not impact local economies and, therefore, did not file a request for a local employment impact statement with the Texas Workforce Commission.

TAKINGS ASSESSMENT

The agency has determined that the proposed governmental action will not affect private real property. The proposed amendments are an activity related to the handling of animals, including requirements for testing, movement, inspection, identification, reporting of disease, and treatment, in accordance with 4 TAC §59.7, and are, therefore, compliant with the Private Real Property Preservation Act in Government Code, Chapter 2007.

REQUEST FOR COMMENT

Comments regarding the proposal may be submitted to Amanda Bernhard, Texas Animal Health Commission, 2105 Kramer Lane, Austin, Texas 78758, by fax at (512) 719-0719 or by email at comments@tahc.texas.gov.

STATUTORY AUTHORITY

The amendments are proposed under the following statutory authority as found in Chapters 161 and 167 of the Texas Agriculture Code. The commission is vested by statute, §161.041(a), with the requirement to protect all livestock, domestic animals, and domestic fowl from disease. The commission is authorized, through §161.041(b), to act to eradicate or control any disease or agent of transmission for any disease that affects livestock.

Pursuant to §161.005, entitled "Commission Written Instruments", the commission may authorize the executive director or another employee to sign written instruments on behalf of the commission. A written instrument, including a quarantine or written notice signed under that authority, has the same force and effect as if signed by the entire commission.

Pursuant to §161.007, entitled "Exposure or Infection Considered Continuing", if a veterinarian employed by the commission determines that a communicable disease exists among livestock, domestic animals, or domestic fowl or on certain premises or that livestock, domestic animals, or domestic fowl have been exposed to the agency of transmission of a communicable disease, the exposure or infection is considered to continue until the commission determines that the exposure or infection has been eradicated through methods prescribed by rule of the commission.

Pursuant to §161.048, entitled "Inspection of Shipment of Animals or Animal Products", the commission may require testing, vaccination, or another epidemiologically sound procedure before or after animals are moved. An agent of the commission is entitled to stop and inspect a shipment of animals or animal products being transported in this state in order to determine if the shipment originated from a quarantined area or herd; or determine if the shipment presents a danger to the public health or livestock industry through insect infestation or through a communicable or noncommunicable disease.

Pursuant to §161.054, entitled "Regulation of Movement of Animals", the commission, by rule, may regulate the movement of animals. The commission may restrict the intrastate movement of animals even though the movement of the animals is unrestricted in interstate or international commerce.

Pursuant to §161.057, entitled "Classification of Areas", the commission by rule may prescribe criteria for classifying areas in the state for disease control. The criteria must be based on sound epidemiological principles. The commission may prescribe different control measures and procedures for areas with different classifications.

Pursuant to §161.061, entitled "Establishment", if the commission determines that a disease listed in §161.041 of this code or an agency of transmission of one of those diseases exists in a place in this state or among livestock, exotic livestock, domestic animals, domestic fowl, or exotic fowl, or that a place in this state or livestock, exotic livestock, domestic animals, domestic fowl, or exotic fowl are exposed to one of those diseases or an agency of transmission of one of those diseases, the commission shall establish a quarantine on the affected animals or on the affected place.

Pursuant to §161.081, entitled "Importation of Animals", the commission by rule may regulate the movement, including movement by a railroad company or other common carrier, of livestock, exotic livestock, domestic animals, domestic fowl, or exotic fowl into this state from another state, territory, or country.

Pursuant to §167.003, entitled "General Powers and Duties of the Commission", the commission shall eradicate all ticks capable of carrying Babesia in this state and shall protect all land, premises, and livestock in this state from those ticks and exposure to those ticks. In carrying out this chapter, the commission may adopt necessary rule.

Pursuant to §167.004, entitled "Classification of Animals or Premises as Infested, Exposed or Free from Exposure", the commission by rule shall define what animals and premises are to be classified as exposed to ticks. The commission shall classify as exposed to ticks livestock that have been on land or in an enclosure that the commission determines to be tick infested or exposed to ticks or to have been tick infested or exposed to ticks before or after the removal of the livestock, unless the commission determines that the infestation or exposure occurred after the livestock were removed and that the livestock did not become infested or exposed before removal.

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

§41.1. *Definition of Terms.*

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

(1) **Adjacent premise**--A premise that borders an exposed or infested premise, including premises separated by roads, double fences, or fordable streams. A premise that would normally be classified as adjacent may be exempted from adjacent premise requirements by a State or Federal epidemiologist if the premise is separated from the exposed or infested premise by double fencing, sufficient to prevent the spread of ticks, with one of the fences being game-proof.

(2) **Animal**--Any domestic, free-range, or wild animal capable of hosting or transporting ticks capable of carrying Babesia, including livestock; zebras, bison, and giraffes; and deer, elk, and other cervid species.

(3) Certificate--A document authorizing movement of livestock issued by an authorized representative of the commission after the livestock have been treated in a manner prescribed by the commission for the area and premise from which they originate.

(4) Check premise--A premise located in a tick eradication quarantine area, temporary preventative quarantine area, or control purpose quarantine area that is not classified as an infested, exposed, or adjacent premise.

(5) Control purpose quarantine area--A premise or property designated by the commission for a systematic inspection of livestock and premises and control of the movement of livestock in order to investigate and control a suspected exposure of animals to ticks outside the tick eradication quarantine area. The boundaries of the area will be determined by evaluation of the barriers to the potential spread of ticks.

(6) Designated Fever Tick Epidemiologist (DFTE)--A State or Federal epidemiologist designated to make decisions concerning the use and interpretation of exposure to fever ticks and to manage the Fever Tick program. The DFTE must be selected jointly by the Executive Director of the commission [~~Commission~~] and the USDA-APHIS, VS representative for Texas. The DFTE has the responsibility to determine the scope of epidemiologic investigations, determine the status of herds, assist in development of individual herd plans, and coordinate fever tick surveillance and eradication programs within his or her geographic area of responsibility. The DFTE has authority to make independent decisions concerning the management of herds and use of property and limiting the impact of wildlife when those decisions are supported by sound fever tick eradication principles.

(7) Dipping or treating--If the commission [~~Commission~~] requires livestock to be dipped, the livestock shall be submerged in a vat. A spray-dip machine may be used in areas where a vat is not reasonably available. Careful hand spraying may be used for easily restrained horses and show cattle, and when specifically authorized, certain zoo or domestic animals. Livestock unable to go through a dipping vat because of size or physical condition may be hand sprayed. The treatment must be paint marked so that it can be identified for at least 17 days. If the commission [~~Commission~~] determines that free-ranging wildlife and exotic animals, which are capable of hosting fever ticks, require treatment, they shall be treated by methods and for the duration of time approved by the commission [~~Commission~~].

(8) Exposed livestock--Any of the following factors shall constitute livestock as being exposed:

(A) Livestock that have entered an infested or exposed premise and have not been dipped and removed from the infested or exposed premise within 14 days after entry.

(B) Livestock that have occupied an exposed premise and have not completed treatment required for movement from an exposed premise.

(C) Livestock that have entered Texas from Mexico without a certificate from the United States Department of Agriculture.

(9) Exposed premise--A premise shall be considered exposed if systematic treatment has not been completed and if either of the following conditions apply:

(A) Ticks have been found on livestock that have been on the premise for less than 14 days.

(B) A premise that has received exposed livestock, or equipment or material capable of carrying ticks from an infested or exposed premise.

(10) Fever Tick Vaccine--A biological treatment administered by injection to an animal that stimulates a potent immune response against fever tick proteins, which prevents the infestation of ticks capable of carrying Babesia.

(11) [(+10)] Free area--An area designated by the commission as being free of ticks or exposure to ticks. The extent of the area will be determined by the appropriate barriers to the potential spread of ticks.

(12) [(+11)] Game proof fence--A fence that has a minimum height of eight feet, consisting of wire mesh of sufficiently small size to prevent or impede the movement of domestic or exotic wildlife over, under, or through the fenced area.

(13) [(+12)] Individual herd plan--A written disease management plan that is developed by the herd or land owner(s) and/or their representative(s), and a State or Federal DFTE to eradicate fever ticks or potential exposure to fever ticks from an affected herd or property. The herd plan will include appropriate treatment frequencies, treatments to be employed, and any additional fever tick management or herd management practices, including vaccination, deemed necessary to eradicate fever ticks from the herd or on an infested or exposed premise in an efficient and effective manner. The plan must be approved by the Executive Director of the commission [~~Commission~~] and USDA-APHIS, VS representative for Texas, and have the concurrence of the DFTE.

(14) [(+13)] Infested livestock--Livestock shall be considered infested if eradication treatment for movement from an infested premise has not been completed and if either of the following conditions apply:

(A) Ticks have been found on livestock.

(B) Livestock which occupy a premise where ticks have been found on livestock that have been on the premise more than 14 days.

(15) [(+14)] Infested premise--A premise where ticks have been found on livestock that have been on the premise for more than 14 days, and systematic treatment has not been completed.

(16) [(+15)] Livestock--Any domestic animal or any free ranging animals found on a premise or captured wild animal that is capable of hosting or transporting ticks capable of carrying babesia (the causative agent of cattle tick fever), including, but not limited to, cattle, horses, mules, jacks, jennets, zebras, buffalo, giraffe, and deer.

(17) [(+16)] Permit--A document issued by an authorized representative of the commission allowing specified movement of livestock.

(18) [(+17)] Premise--An area which can be defined by boundaries of recognizable physical barriers that prevent livestock from crossing the boundaries under ordinary circumstances; or an area that livestock do not ordinarily inhabit that the commission defines by recognizable features.

(19) [(+18)] Premise inspection--A routine inspection by an authorized representative of the commission of premise boundaries and the livestock within for the purpose of documenting exposure of the premise.

(20) [(+19)] Premise under vacation--A premise from which all livestock have been removed as prescribed by the commission.

(21) [(+20)] Range inspection of livestock--An inspection of livestock to see the animal close enough to detect ticks on the animal.

(22) [(21)] Scratch inspection of livestock--An inspection of livestock by an authorized representative of the commission in an approved facility that allows the inspector to touch and see all parts of the livestock.

(23) [(22)] Temporary preventative quarantine area--An area designated by the commission for systematic inspection and treatment of livestock and premises, and control of movement of livestock, in order to detect and eradicate infestation and exposure from infested or exposed premises outside the tick eradication quarantine area. The extent of the area will be determined by evaluating the barriers to the potential spread of ticks. This is also designated as a "Blanket Disease Quarantine."

(24) [(23)] The commission--The Texas Animal Health Commission.

(25) [(24)] Tick--Any tick capable of transmitting bovine Babesiosis (cattle tick fever or bovine piroplasmosis).

(26) [(25)] Tick eradication quarantine area--An area designated by the commission for systematic inspection and treatment of livestock and premises, and control of movement of livestock, in order to detect and eradicate infestation from infested or exposed premises. The extent of the area will be determined by evaluating the barriers to the potential spread of ticks. This is the permanent quarantine area which is designated in §§41.14 - 41.22 of this chapter (relating to Quarantine Line; Defining and Establishing Tick Eradication Areas), and in the United States Department of Agriculture Code of Federal Regulations Part 72.5, parallel to the Rio Grande River, commonly known as the buffer zone or systematic area.

(27) [(26)] Treatment--A procedure or management practice used on an animal to prevent the infestation of, control or eradicate ticks capable of carrying Babesia.

§41.8. Dipping, Treatment, and Vaccination of Animals.

(a) General Requirements:

(1) All scratch inspections, dipping, treatment, and vaccination prescribed in this section must be done under the supervision of a representative authorized by the commission.

(2) All scratch inspections, dipping, treatment, or vaccination must be done under instructions issued by the commission. All requirements will be in written form directed to the owner or caretaker. An inspector for the commission will deliver the instructions in person along with a copy of these regulations. All premise boundaries will be listed in the instructions.

(3) The owner or caretaker of livestock on infested and exposed premises must comply with the TAHC approved Quarantine Schedule as follows:

(A) The starting date for infested premises for Table I (Pasture Treatment or Vacation Schedule, South of Highway 90) and Table II (Pasture Treatment or Vacation Schedule, North of Highway 90), is the date of the first clean dipping of 100% of the livestock.

(B) The starting date for exposed premises for Table I and Table II is when 100% of the livestock on the premise have been dipped.

(C) Copies of Table I (Pasture Treatment or Vacation Schedule, South of Highway 90) and Table II (Pasture Treatment or Vacation Schedule, North of Highway 90) may be obtained from the Texas Animal Health Commission, P.O. Box 12966, Austin, Texas 78711-2966.

Figure: 4 TAC §41.8(a)(3)(C)

(4) The owner or caretaker must gather and present all livestock for scratch inspection, dipping, treatment, or vaccination required by the commission. The owner or caretaker is responsible for all costs associated with and labor necessary for presenting the owner or caretaker's cattle for scratch inspection, dipping, treatment, or vaccination at the location prescribed by the commission.

(b) Requirements for Dipping, Treatment, or Vaccination:

(1) Dipping Requirements:

(A) The owner or caretaker of livestock on infested or exposed premises must present the livestock to be scratch inspected and dipped with subsequent dipping every seven to 14 days until the livestock are moved from the premise in accordance with these regulations, except as provided in subsection (a)(3) of this section.

(B) The 14-day interval may be extended due to circumstances beyond the control of the owner upon approval by an authorized representative of the commission. In no event will the extension be more than three days. If the extension is granted, no certificate for movement will be issued after the 14th day, and the next dip must be on the original 14-day schedule.

(C) The scratch inspection and first dip must be within 14 days from the date infestation or exposure is discovered unless otherwise approved by the commission.

(D) A dip is not official unless 100% of the livestock within the premise affected are dipped on schedule.

(E) The commission will authorize for use in dipping only those dips that have been approved by the Animal and Plant Health Inspection Service of the United States Department of Agriculture and the Texas Animal Health Commission for use in official dipping to rid animals of the tick.

(F) The concentration of the dipping chemical used must be maintained in the percentage specified for official use by means of the approved vat management techniques established for the use of the agent; or, if applicable, by an officially approved vat side test or field test of the commission.

(G) If the commission requires livestock to be dipped, the livestock shall be submerged in a vat. A spray-dip machine may be used in areas where a vat is not reasonably available.

(H) Careful hand spraying may be used for easily restrained horses and show cattle, and when specifically authorized by a commission representative, certain zoo or domestic animals.

(I) Livestock unable to go through a dipping vat because of size or physical condition, as determined by a commission representative, may be hand sprayed.

(J) The dip treatment must be paint marked on the animals so that it can be identified for as treated for at least 17 days after the treatment.

(2) Authorized Treatment Requirements:

(A) Following the first clean dipping of 100% of the livestock, the cattle may be treated with injectable doramectin in lieu of systematic dipping. The owner or caretaker of cattle on an infested or exposed premise must present the livestock to be scratch inspected and treated with injectable doramectin every 25-28 days until the livestock are moved from the premises in accordance with these regulations, except as provided in subsection (a)(3) of this section.

(B) Treatment of doramectin shall be administered by subcutaneous injection by a representative of the commission.

(C) The owner or caretaker must comply with the slaughter withholding period (35 days) of doramectin by holding cattle at the premise of origin until the withdrawal period has been completed.

(D) A treatment is not official unless 100% of the livestock within the premise affected are treated on schedule.

(E) Free-ranging wildlife or exotic livestock that are found on infested or exposed premises, and which are capable of hosting fever ticks will be treated by methods approved by the commission and for the length of time specified by the commission.

(i) Ivermectin medicated corn may be administered to free-ranging wildlife or exotic livestock by a representative of the commission following the close of the hunting season, provided that treatment is terminated at least 60 days prior to the beginning of the next hunting season to comply with the required withdrawal period.

(ii) Permethrin impregnated roller devices may be used for topical treatment of free-ranging wildlife or exotic livestock during periods when ivermectin medicated corn is not administered. The commission may specify the use of other pesticides for treatment of wildlife or exotic livestock when deemed necessary to control and eradicate fever ticks.

(3) Vaccination Requirements:

(A) The fever tick vaccine shall be administered by employees or authorized agents of the USDA/APHIS/Veterinary Services or the commission.

(B) The owner or caretaker must comply with the 60 day slaughter withholding period, or other slaughter withholding time-frame as specified by the label. The owner or caretaker must hold vaccinated cattle at the premise of origin until the withdrawal period is has been completed.

(C) In addition to any dipping or treatment required by this section, beef cattle two months of age or older located within the tick eradication quarantine area shall be vaccinated with the fever tick vaccine at intervals prescribed by the commission. The vaccine must be administered when cattle are gathered and presented for annual inspection as required by §41.9 of this chapter (relating to Vacation and Inspection of a Premise) and at other times specified by the commission.

(D) In addition to any dipping or treatment required by this section, the commission may require fever tick vaccination of beef cattle two months of age and older located within the temporary preventative quarantine area, control purpose quarantine area or other beef cattle or premises epidemiologically determined by the commission to be at an increased risk for fever ticks. The cattle shall be vaccinated at intervals prescribed by the commission.

(c) Herd Plan and Protest. Each premise within a tick eradication quarantine area, temporary preventative quarantine area, or control purpose quarantine area will be classified by the commission as an infested, exposed, adjacent, or check premise and is required to execute a herd management plan and remain under restrictions until no evidence of fever ticks is disclosed or a complete epidemiologic investigation fails to disclose evidence of exposure to fever ticks, with the concurrence of the DFTE. A person may protest an initial test or a herd plan for each premise classified as increased risk for fever ticks.

(1) To protest, the responsible person must request a meeting, in writing, with the Executive Director of the commission within 15 days of receipt of the herd plan or notice of an initial test and set forth a short, plain statement of the issues that shall be the subject of the protest, after which:

(A) the meeting will be set by the Executive Director no later than 21 days from receipt of the request for a meeting;

(B) the meeting or meetings shall be held in Austin; and

(C) the Executive Director shall render his decision in writing within 14 days from date of the meeting.

(2) Upon receipt of a decision or order by the executive director which the herd owner wishes to appeal, the herd owner may file an appeal within 15 days in writing with the Chairman of the commission and set forth a short, plain statement of the issues that shall be the subject of the appeal.

(3) The subsequent hearing will be conducted pursuant to the provisions of the Administrative Procedure and Texas Register Act, and Chapter 32 of this title (relating to Hearing and Appeal Procedures).

(4) If the Executive Director determines, based on epidemiological principles, that immediate action is necessary, the Executive Director may shorten the time limits to not less than five days. The herd owner must be provided with written notice of any time limits so shortened.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 24, 2016.

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Gene Snelson

General Counsel

Texas Animal Health Commission

Earliest possible date of adoption: April 10, 2016

For further information, please call: (512) 719-0722



4 TAC §41.8

The Texas Animal Health Commission (commission) proposes the repeal of §41.8, concerning Dipping and Treatment of Livestock, in Chapter 41, which is entitled "Fever Ticks".

Elsewhere in this issue of the *Texas Register*, the commission proposes new §41.8, concerning Dipping, Treatment, and Vaccination of Animals, which replaces the repealed section in its entirety.

FISCAL NOTE

Ms. Larissa Schmidt, Director of Administration, Texas Animal Health Commission, has determined there will be no significant additional fiscal implications for state or local government as a result of repealing the rule.

PUBLIC BENEFIT NOTE

Ms. Schmidt has also determined that the public benefit anticipated as a result of repealing the rule will be that the proposed new section will clarify and better organize the fever tick dipping, treatment, and new vaccination requirements.

LOCAL EMPLOYMENT IMPACT STATEMENT

In accordance with the Texas Government Code §2001.022, this agency has determined that the proposed repeal will not impact local economies and, therefore, did not file a request for a local employment impact statement with the Texas Workforce Commission.

TAKINGS ASSESSMENT

The agency has determined that the proposed repeal will not affect private real property and is, therefore, compliant with the Private Real Property Preservation Act in Government Code, Chapter 2007.

REQUEST FOR COMMENT

Comments regarding the proposal may be submitted to Amanda Bernhard, Texas Animal Health Commission, 2105 Kramer Lane, Austin, Texas 78758, by fax at (512) 719-0719 or by email at comments@tahc.texas.gov.

STATUTORY AUTHORITY

The repeal is authorized by the Texas Agriculture Code §161.046, which provides the commission with authority to adopt rules relating to the protection of livestock, exotic livestock, domestic fowl or exotic fowl, as well as Texas Government Code §2001.039, which authorizes a state agency to repeal a rule.

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

§41.8. *Dipping and Treatment of Livestock.*

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 24, 2016.

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Gene Snelson

General Counsel

Texas Animal Health Commission

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For further information, please call: (512) 719-0722



TITLE 19. EDUCATION

PART 7. STATE BOARD FOR EDUCATOR CERTIFICATION

CHAPTER 230. PROFESSIONAL EDUCATOR PREPARATION AND CERTIFICATION SUBCHAPTER C. ASSESSMENT OF EDUCATORS

19 TAC §230.21, §230.25

The State Board for Educator Certification (SBEC) proposes amendments to 19 TAC §230.21 and §230.25, concerning professional educator preparation and certification. The sections establish guidelines and procedures for the assessment of educators. The proposed amendments to 19 TAC §230.21 and §230.25 would implement the requirement from the 84th Texas Legislature, Regular Session, 2015, to enforce a limit of five attempts on any certification examination, unless the SBEC approves an additional attempt based on an individual's demonstration of good cause. The proposed amendments to 19 TAC §230.21 and §230.25 would also implement a clarification from the 84th Texas Legislature, Regular Session, 2015, that the commissioner of education approves the satisfactory level of performance required for certification examinations and would

reflect input received from the SBEC, stakeholders, and Texas Education Agency (TEA) staff.

§230.21. *Educator Assessment*

Subsection (a) would be removed because the basic skills assessment that is required for admission to an educator preparation program (EPP) is described in 19 TAC Chapter 227. Subsections (b)-(e) would be relettered accordingly.

In accordance with the Texas Education Code (TEC), §21.048, as amended by House Bill (HB) 2205, 84th Texas Legislature, Regular Session, 2015, language would be amended in proposed subsection (a) to limit the number of times an individual may retake a certification examination to four unless the limitation is waived for good cause. A candidate seeking a waiver of the limitation would be responsible for providing proof of the good cause.

Proposed subsection (a)(1) would be added to define an examination retake. An examination retake would be defined as a second or subsequent attempt to pass any examination required for the issuance of a certificate, including an individual core subject examination that is part of the overall examination required for the issuance of a Core Subjects certificate. An examination score that is cancelled would not be considered an examination retake.

Proposed subsection (a)(2) would be added to define good cause in one of six ways. The first four ways would be based on the candidate's highest score on an examination and a conditional standard error of measurement (CSEM) table that would be published annually on the TEA website. A CSEM is the measure of the precision of scores for an assessment based on a specific score point and the design of the assessment. CSEM would be used in this context to determine how likely a candidate will pass an examination on his or her next attempt if a candidate completed a number of clock-hours of additional educational activity. If a candidate's highest examination score was within one, two, or three CSEMs from passing, the candidate would need to participate in 50, 100, or 150 clock-hours of additional educational activity, respectively. If a candidate's highest examination score was not within three CSEMs from passing, the candidate would need to participate in 200 clock-hours of additional educational activity.

If a candidate needs a waiver for more than one of the individual core subject examinations that are part of the overall examination required for the issuance of a Core Subjects certificate, the fifth way of determining good cause would be the combination of the number of clock-hours of educational activities required for each individual core subject examination as described in the first four ways of determining good cause. The maximum number of required clock-hours could not exceed 300 clock-hours. The number of clock-hours for each examination may be divided equally based on the number of examinations in the waiver request, but the number of clock-hours for an examination shall not be less than 50 for each examination.

The sixth way of determining good cause would be if a CSEM is not appropriate for an examination. One reason a CSEM may not be appropriate for an examination is if an examination does not use a scale score. The examinations that are currently used for certification and do not use a scale score are the Texas Assessment of Sign Communication examinations and the language examinations administered by the American Council for the Teaching of Foreign Languages. A second reason a CSEM may not be appropriate for an examination is if an examination

does not have enough test takers to determine a CSEM. The examinations that are currently used for certification and have very low numbers of test takers are the Languages other than English Latin examination and the examinations administered by the American Association of Family and Consumer Sciences. In the event that a candidate was not successful after five attempts on an examination that did not have a CSEM, the candidate would request a waiver, and TEA staff would identify individuals who are familiar and knowledgeable with the examination content. These individuals would review the candidate's performance on the five most recent examinations, identify the areas of deficit, and determine the number of clock-hours of additional educational activity required to demonstrate good cause.

Proposed subsection (a)(3) would be added to define educational activity. An educational activity would be provided by an approved EPP or an approved continuing professional education (CPE) provider or sponsor. Approved CPEs currently include all accredited institutions of higher education, education service centers, Texas public school districts, accredited private schools, and non-profit organizations that have offered professional development in Texas for at least five years. Approved CPEs also currently include private entities and individuals who have been approved by TEA staff to offer CPE activities. An educational activity would need to be directly related to the knowledge and skill competencies in which the candidate answered less than 70 percent of questions correctly on the past five examinations. A competency is a grouping of knowledge and skills on a certification examination that defines what an entry-level educator in Texas public schools should know and be able to do. To provide consistency among candidates when identifying deficit competencies, a candidate would add the number of questions answered correctly in each competency on each of the five most recent examinations, add the number of questions asked for each competency on each of the five most recent examinations, and then, for each competency, divide the total number of questions answered correctly by the total number of questions asked. If a candidate did not correctly answer 70 percent of the questions in a competency across the past five examinations, the candidate would identify the competency as a deficit area that should be addressed by an educational activity.

Proposed subsection (a)(4) would be added to identify how a candidate must document an educational activity. This documentation would include the provider, sponsor, or program's name, address, telephone number, and email address; the name of the educational activity; the competency or competencies addressed by the educational activity; the provider, sponsor, or program's description of the educational activity; and the provider, sponsor, or program's written verification of the dates of participation in and the number of clock-hours completed for the educational activity.

One semester credit hour earned at an accredited institution of higher education would be equivalent to 15 clock-hours. Clock-hours completed before the most recent examination attempt or after a request for a waiver is submitted would not count toward meeting the educational activity required to show good cause for a waiver.

Proposed subsection (a)(5) would be added to identify how a candidate would request a waiver. A candidate seeking certification based on the completion of an EPP would need the approval of an EPP to request a waiver. Candidates seeking certification through routes other than an EPP would need to meet the eligibility requirements of the appropriate route. Beginning September

1, 2016, a candidate would need to pay a waiver request fee of \$160, which is the same amount for an out-of-state/out-of-country review of credentials. A candidate would need to request a waiver on a form developed by TEA staff and approved by the SBEC. Waiver requests would not be accepted for 45 calendar days after the fourth unsuccessful retake, 90 calendar days after a denied waiver request, or 180 calendar days after the most recent unsuccessful attempt that was the result of an approved waiver request. After a waiver request is received by TEA staff, the request would be reviewed and TEA staff would make a decision to approve or deny the request based on the criteria in proposed §230.21(a)(2)-(5). An applicant who does not meet the criteria in proposed §230.21(a)(2)-(5) may appeal to the SBEC for a final determination of good cause. A determination by the SBEC is final and may not be appealed.

In accordance with the TEC, §21.048, as amended by HB 2205, 84th Texas Legislature, Regular Session, 2015, language would be amended in proposed subsection (d) to clarify that the commissioner of education approves the satisfactory level of performance required for each certification examination. The proposed amendment would not change the authority of the SBEC to approve a schedule of examination fees and a plan for administering the examinations. Proposed subsection (e) would be added to list the appropriate examinations required for certification in a figure.

Minor technical edits would be proposed in subsections (f) and (g) to conform to *Texas Register* style and format requirements and update cross references.

§230.25. Test Exemptions for Persons with a Hearing Impairment

Minor technical edits would be proposed in subsection (b)(2) to align terminology with current SBEC rules.

The proposed amendments would have no reporting requirements; however, there would be procedural implications. Proposed 19 TAC §230.21(a)(5)(C) would require a person to request a waiver of a limitation of certification testing in writing on forms developed by the TEA staff. Proposed 19 TAC §230.21(a)(4) would require a person requesting a waiver to provide documentation of educational activity that is evidence of a substantial change in learning. This documentation would be included as part of the waiver request form. Other data that would be collected in the form includes an individual's TEA ID number and recent certification examination score information. The proposed amendments would have no locally maintained paperwork requirements.

FISCAL NOTE. Ryan Franklin, associate commissioner for educator leadership and quality, has determined that for the first five-year period the proposed amendments are in effect there are fiscal implications as a result of the proposed amendment to 19 TAC §230.21. The following fiscal implications are based on offsetting costs and revenues for state government (TEA) and costs for persons (individuals) for fiscal years (FYs) 2017-2020. The proposed new fee for a waiver request in 19 TAC §230.21 would cover the cost of administering the waiver requests so there is neither a projected increase nor a projected loss in revenue for the TEA. The fee collection estimates are based on the number of people who attempted a test for the fifth time over the past four years. While the numbers of people attempting a fifth test have increased over the past four years, the TEA expects fewer people to reach a fifth attempt after the proposed amendments are in effect due to the various requirements for the waiver

application as well as other proposed rules that are related to the use of certification examination results for EPP accountability.

The proposed amendment to 19 TAC §230.21 includes a new waiver request fee of \$160. This fee would be paid by an individual who requests a waiver to the four-retest limitation. This fee would adequately cover the TEA cost of administering the waiver request. For FY 2016 there would be no anticipated fiscal implications since the proposed amendment to §230.21 that would establish a \$160 waiver application fee would not be implemented until the next fiscal year. The TEA estimates the total costs to state government at \$62,592 for FY 2017, \$49,800 for FY 2018, \$35,168 for FY 2019, and \$21,912 for FY 2020. The TEA estimates the total costs to individuals at \$62,592 for FY 2017, \$49,800 for FY 2018, \$35,168 for FY 2019, and \$21,912 for FY 2020. The costs for state government would be offset by the estimated revenues from the fees collected from individuals.

The TEA staff has determined that there is no additional fiscal impact on local governments as a result of enforcing or administering the proposed amendments.

PUBLIC BENEFIT/COST NOTE. Mr. Franklin has determined that for the first five-year period the proposed amendments are in effect the public and student benefit anticipated as a result of the proposed amendments would be the continuation of requirements relating to certification, fees, procedures for testing and certificate issuance, educational aides, and permits for professional educator preparation and certification. The anticipated economic cost to persons who are required to comply with the proposed amendments is described earlier under Fiscal Note.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND MICROBUSINESSES. There is no direct adverse economic impact for small businesses and microbusinesses; therefore, no regulatory flexibility analysis, specified in Texas Government Code, §2006.002, is required.

REQUEST FOR PUBLIC COMMENT. The public comment period on the proposal begins March 11, 2016, and ends April 11, 2016. The SBEC will take registered oral and written comments on the proposed amendments of 19 TAC §230.21 and §230.25 at the April 15, 2016 meeting in accordance with the SBEC board operating policies and procedures. Comments on the proposal may be submitted to Cristina De La Fuente-Valadez, Rulemaking, Texas Education Agency, 1701 North Congress Avenue, Austin, Texas 78701, (512) 475-1497. Comments may also be submitted electronically to sbecrules@tea.texas.gov or faxed to (512) 463-5337. All requests for a public hearing on the proposed amendments submitted under the Administrative Procedure Act must be received by the Department of Educator Leadership and Quality, Texas Education Agency, 1701 North Congress Avenue, Austin, Texas 78701, Attention: Mr. Ryan Franklin, associate commissioner for educator leadership and quality, not more than 14 calendar days after notice of the proposal has been published in the *Texas Register* on March 11, 2016.

STATUTORY AUTHORITY. The amendments are proposed under the Texas Education Code (TEC), §21.031(a), which states that the State Board for Educator Certification (SBEC) shall regulate and oversee all aspects of the certification, continuing education, and standards of conduct of public school educators; §21.031(b), which states that in proposing rules under the TEC, Chapter 21, Subchapter B, the SBEC shall ensure that all candidates for certification or renewal of certification demonstrate the

knowledge and skills necessary to improve the performance of the diverse student population of this state; §21.041(a), which allows the SBEC to adopt rules as necessary for its own procedures; §21.041(b)(1), which requires the SBEC to propose rules that provide for the regulation of educators and the general administration of the TEC, Chapter 21, Subchapter B, in a manner consistent with the TEC, Chapter 21, Subchapter B; §21.041(b)(4), which requires the SBEC to propose rules that specify the requirements for the issuance and renewal of an educator certificate; §21.041(b)(7), which requires the SBEC to propose rules that provide for disciplinary proceedings, including the suspension or revocation of an educator certificate, as provided by the Texas Government Code, Chapter 2001; §21.041(b)(8), which requires the SBEC to propose rules that provide for the enforcement of an educator's code of ethics; §21.041(c), which requires the SBEC to propose a rule adopting a fee for the issuance and maintenance of an educator certificate that is adequate to cover the cost of administration of the TEC, Chapter 21, Subchapter B; §21.045(a)(1), as amended by House Bill (HB) 2205, 84th Texas Legislature, Regular Session, 2015, which authorizes the SBEC to propose rules necessary to establish standards to govern the continuing accountability of all educator preparation programs based on the following information that is disaggregated with respect to race, sex, and ethnicity: results of the certification examinations prescribed under the TEC, §21.048(a); §21.048(a), as amended by HB 2205, 84th Texas Legislature, Regular Session, 2015, which requires the SBEC to propose rules prescribing comprehensive examinations for each class of certificate issued by the SBEC, specifies that the commissioner of education shall determine the satisfactory level of performance required for each certification examination, and that the commissioner shall require a satisfactory level of examination performance in each core subject covered by the generalist certification examination; §21.048(a-1), as amended by HB 2205, 84th Texas Legislature, Regular Session, 2015, which states that the SBEC may not require that more than 45 days elapse before a person may retake an examination and a person may not retake an examination more than four times, unless the SBEC waives the limitation for good cause as prescribed by the SBEC; §21.048(a-2), as added by HB 2205, 84th Texas Legislature, Regular Session, 2015, which states that for purposes of the limitation imposed by Subsection (a-1) on the number of administrations of an examination, a person who initially took an examination before September 1, 2015, may retake the examination up to four times after that date, regardless of the number of times that the person attempted to perform satisfactorily on the examination before that date. This subsection expires September 1, 2018; §21.048(b), which states that the SBEC may not administer a written examination to determine the competence or level of performance of an educator who has a hearing impairment unless the examination has been field tested to determine its appropriateness, reliability, and validity as applied to, and minimum acceptable performance scores for, persons with hearing impairments; §21.048(c), which states that an educator who has a hearing impairment is exempt from taking a written examination for a period ending on the first anniversary of the date on which the SBEC determines, on the basis of appropriate field tests, that the examination complies with the standards specified in subsection (b) of this section; §21.048(c-1), as amended by HB 2205, 84th Texas Legislature, Regular Session, 2015, which states that the results of an examination administered under this section are confidential and are not subject to disclosure under the Texas Government Code, Chapter 552, unless the disclosure is regarding notification to a parent of the assignment of an un-

certified teacher to a classroom as required by the TEC, §21.057; and §21.048(d), which states the definitions for hearing impairment, reliability, and validity when used in the TEC, §21.048; and the Texas Occupations Code (TOC), §54.003(a), which defines "dyslexia" as having the same meaning assigned by the TEC, §51.970; §54.003(b), which states that, for each licensing examination administered by a state agency, the agency shall provide reasonable examination accommodations to an examinee diagnosed as having dyslexia; and §54.003(c), which states that each state agency shall adopt rules necessary to implement the TOC, §54.003, including rules to establish the eligibility criteria an examinee must meet for accommodation under the TOC, §54.003.

CROSS REFERENCE TO STATUTE. The proposed amendments implement the TEC, §§21.031; 21.041(a), (b)(1), (4), (7), and (8), and (c); 21.045(a)(1), as amended by HB 2205, 84th Texas Legislature, Regular Session, 2015; 21.048, as amended by HB 2205, 84th Texas Legislature, Regular Session, 2015; and the TOC, §54.003.

§230.21. *Educator Assessment.*

~~[(a) An individual seeking admission to an approved educator preparation program (EPP) for initial certification must be assessed for basic skills in reading, written communication, and mathematics, unless the individual holds a bachelor's degree or higher from an accredited institution of higher education.]~~

(a) [(b)] A candidate seeking certification as an educator must pass the examination(s) required by the Texas Education Code (TEC), §21.048, and the State Board for Educator Certification (SBEC) in §233.1(e) of this title (relating to General Authority) and shall not retake an examination more than four times, unless the limitation is waived for good cause. The burden of proof shall be upon the candidate to demonstrate good cause.

(1) For the purposes of the retake limitation described by the TEC, §21.048, an examination retake is defined as a second or subsequent attempt to pass any examination required for the issuance of a certificate, including an individual core subject examination that is part of the overall examination required for the issuance of a Core Subjects certificate as described in §233.2 of this title (relating to Core Subjects; Generalist). An examination score that is cancelled is not considered an examination retake.

(2) Good cause is:

(A) the candidate's highest score on an examination is within one conditional standard error of measurement (CSEM) of passing and the candidate has completed 50 clock-hours of educational activities. CSEMs will be published annually on the Texas Education Agency (TEA) website;

(B) the candidate's highest score on an examination is within two CSEMs of passing and the candidate has completed 100 clock-hours of educational activities;

(C) the candidate's highest score on an examination is within three CSEMs of passing and the candidate has completed 150 clock-hours of educational activities;

(D) the candidate's highest score on an examination is not within three CSEMs of passing and the candidate has completed 200 clock-hours of educational activities;

(E) if the candidate needs a waiver for more than one of the individual core subject examinations that are part of the overall examination required for the issuance of a Core Subjects certificate, the candidate has completed the number of clock-hours of educational

activities required for each individual core subject examination as described in subparagraphs (A)-(D) of this paragraph up to a maximum of 300 clock-hours. The number of clock-hours for each examination may be divided equally based on the number of examinations in the waiver request, but the number of clock-hours for an examination shall not be less than 50; or

(F) if a CSEM is not appropriate for an examination, the TEA staff will identify individuals who are familiar and knowledgeable with the examination content to review the candidate's performance on the five most recent examinations, identify the deficit competency or competencies, and determine the number of clock-hours of educational activities required.

(3) Educational activities are defined as:

(A) institutes, workshops, seminars, conferences, interactive distance learning, video conferencing, online activities, undergraduate courses, graduate courses, training programs, in-service, or staff development given by an approved continuing professional education provider or sponsor, pursuant to §232.17 of this title (relating to Pre-Approved Professional Education Provider or Sponsor) and §232.19 of this title (relating to Approval of Private Companies, Private Entities, and Individuals), or an approved educator preparation program (EPP), pursuant to §228.10 of this title (relating to Approval Process); and

(B) being directly related to the knowledge and skills included in the certification examination competency or competencies in which the candidate answered less than 70 percent of competency questions correctly. The formula for identifying a deficit competency is the combined total of correct answers for each competency on the five most recent examinations divided by the combined total of questions for each competency on the five most recent examinations.

(4) Documentation of educational activities that a candidate must submit includes:

(A) the provider, sponsor, or program's name, address, telephone number, and email address. The TEA staff may contact the provider, sponsor, or program to verify an educational activity;

(B) the name of the educational activity (e.g., course title, course number);

(C) the competency or competencies addressed by the educational activity as determined by the formula described in paragraph (3)(B) of this subsection;

(D) the provider, sponsor, or program's description of the educational activity (e.g., syllabus, course outline, program of study); and

(E) the provider, sponsor, or program's written verification of the candidate's completion of the educational activity (e.g., transcript, certificate of completion). The written verification must include:

(i) the provider, sponsor, or program's name;

(ii) the candidate's name;

(iii) the name of the educational activity;

(iv) the date(s) of the educational activity; and

(v) the number of clock-hours completed for the educational activity. Clock-hours completed before the most recent examination attempt or after a request for a waiver is submitted shall not be included. One semester credit hour earned at an accredited institution of higher education is equivalent to 15 clock-hours.

(5) To request a waiver of the limitation, a candidate must meet the following conditions:

(A) the candidate is otherwise eligible to take an examination. A candidate seeking a certificate based on completion of an EPP must have the approval of an EPP to request a waiver;

(B) the candidate pays the non-refundable waiver request fee of \$160;

(C) the candidate requests the waiver of the limitation in writing on forms developed by the TEA staff; and

(D) the request for the waiver is postmarked not earlier than:

(i) 45 calendar days after an unsuccessful attempt at the fourth retake of an examination as defined in the TEC, §21.048; or

(ii) 90 calendar days after the date of the most recent denied waiver of the limitation request; or

(iii) 180 calendar days after the date of the most recent unsuccessful examination attempt that was the result of the most recently approved request for waiver of the limitation.

(6) The TEA staff shall administratively approve each application that meets the criteria specified in paragraphs (2)-(5) of this subsection.

(7) An applicant who does not meet the criteria in paragraphs (2)-(5) of this subsection may appeal to the SBEC for a final determination of good cause. A determination by the SBEC is final and may not be appealed.

(b) [(e)] A candidate seeking a standard certificate as an educator based on completion of an approved EPP may take the appropriate certification examination(s) required by subsection (a) [(b)] of this section only at such time as the EPP determines the candidate's readiness to take the examinations, or upon successful completion of the EPP, whichever comes first.

(c) [(d)] The holder of a lifetime Texas certificate effective before February 1, 1986, must pass examinations prescribed by the SBEC to be eligible for continued certification, unless the individual has passed the Texas Examination of Current Administrators and Teachers (TECAT).

(d) [(e)] The commissioner of education [For an examination or other assessment required by law or under the provisions of this title, the SBEC] approves the satisfactory level of performance required for certification examinations, and the SBEC approves[;] a schedule of examination fees[;] and a plan for administering the examinations [examination].

(e) The appropriate examination(s) required for certification are specified in the figure provided in this subsection. Figure: 19 TAC §230.21(e)

(f) Scores from examinations required under this title must be made available to the examinee, the TEA [Texas Education Agency (TEA)] staff, and, if appropriate, the EPP from which the examinee will seek a recommendation for certification.

(g) The following provisions concern test security and confidential integrity.

(1) An educator who participates in the development, design, construction, review, field testing, or validation of an examination shall not reveal or cause to be revealed the contents of the examination to any other person.

(2) An educator who administers an examination shall not:

(A) allow or cause an unauthorized person to view any part of the examination;

(B) copy, reproduce, or cause to be copied or reproduced any part of the examination;

(C) reveal or cause to be revealed the contents of the examination;

(D) correct, alter, or cause to be corrected or altered any response to a test item contained in the examination;

(E) provide assistance with any response to a test item contained in the examination or cause assistance to be provided; or

(F) deviate from the rules governing administration of the examination.

(3) An educator who violates subsection (a) [(b)] or (b) [(e)] of this section is subject to sanction in accordance with the provisions of the TEC, §21.041(b)(7), and Chapter 249 of this title (relating to Disciplinary Proceedings, Sanctions, and Contested Cases).

(4) An educator who is an examinee shall not:

(A) copy, reproduce, or cause to be copied or reproduced any test item contained in the examination;

(B) provide assistance with any response to a test item contained in the examination, or cause assistance to be provided;

(C) solicit or accept assistance with any response to a test item contained in the examination;

(D) deviate from the rules governing administration of the examination; or

(E) otherwise engage in conduct that amounts to cheating, deception, or fraud.

(5) An educator who violates this subsection is subject to:

(A) sanction in accordance with the provisions of the TEC, §21.041(b)(7), and Chapter 249 of this title;

(B) voiding of a score from an examination in which a violation specified in this subsection occurred; and

(C) disallowance and exclusion from future examinations either in perpetuity or for a period of time that serves the best interests of the education profession.

§230.25. Test Exemptions for Persons with a Hearing Impairment.

(a) A candidate who has a hearing impairment may request exemption from educator certification and competence examinations that have not been field-tested for appropriateness, reliability, and validity as applied to persons with hearing impairments.

(b) A request for such an exemption shall include:

(1) a report by a licensed audiologist documenting that the candidate has a hearing impairment so severe that the person cannot process written linguistic information. The report may not be dated more than one year from the date of the request for the exemption and should address the relationship between the candidate's age at the onset or diagnosis of hearing loss and the candidate's ability to process written linguistic information; and

(2) a recommendation for exemption and certification of the candidate by an approved Texas educator preparation program (EPP). The recommendation shall be based on the EPP's determination of the candidate's qualification for the exemption and competency in each certification class and category [content field] in which certifica-

tion is sought. The EPP shall make and document its determination of educator standards [econtent field] competency, as follows:

(A) by reviewing and approving transcripts from an accredited institution of higher education that demonstrate that the candidate has completed 24 semester credit hours in the educator standards [econtent field], including 12 semester credit hours of upper division coursework, and documenting that the coursework is aligned to the Texas educator [econtent field] standards;

(B) if an EPP uses an alternative assessment to measure competency in any certification class and category [econtent field] in which a certification is being sought, by documenting the method and validity of the means of assessment, the results of the assessment, and the alignment of the assessment to the applicable Texas educator [econtent field] standards; and

(C) for the Texas pedagogy and professional responsibilities examination, by documenting successful completion of EPP coursework and training covering educator standards for the grade level for which certification is sought.

(c) The TEC, §21.048, provides that the SBEC may not administer a certification examination that has not been field-tested for appropriateness, reliability, and validity to a person who is unable to process linguistic information. An educator who has been granted such an exemption may not subsequently take any other such certification examination without submitting a new audiologist's report that addresses the prior audiologist's report and documents that the educator is now able to process written linguistic information.

(d) This section does not affect the procedures for one-year certificates, extensions, and permits based on out-of-state credentials pursuant to §230.113 of this title (relating to Requirements for Texas Certificates Based on Certification from Other States or Territories of the United States), but, to be issued a standard certificate, a person must either satisfy the applicable examination requirements or be recommended for certification by an EPP.

(e) As with other EPP completion and admission documentation under §228.40 of this title (relating to Assessment and Evaluation of Candidates for Certification and Program Improvement), all documentation required under this section shall be retained by an EPP for five years and is subject to audit by Texas Education Agency staff.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 29, 2016.

TRD-201601006

Cristina De La Fuente-Valadez

Director, Rulemaking, Texas Education Agency

State Board for Educator Certification

Earliest possible date of adoption: April 10, 2016

For further information, please call: (512) 475-1497



CHAPTER 232. GENERAL CERTIFICATION PROVISIONS

SUBCHAPTER A. CERTIFICATE RENEWAL AND CONTINUING PROFESSIONAL EDUCATION REQUIREMENTS

The State Board for Educator Certification (SBEC) proposes amendments to 19 TAC §§232.7, 232.9, 232.11, 232.13, 232.15, 232.17, 232.19, 232.21, and 232.23 and repeal of 19 TAC §232.27, concerning certificate renewal and continuing professional education (CPE) requirements. The sections establish the renewal requirements relating to types and classes of certificates issued and CPE. The proposed amendments to 19 TAC §§232.7, 232.9, 232.11, 232.13, 232.15, 232.17, 232.19, 232.21, and 232.23 would implement the requirement from the 84th Texas Legislature, Regular Session, 2015, to allow educators to receive credit for completion of an instructional course on the use of an automated external defibrillator (AED) and would further clarify certificate renewal and CPE requirements. The proposed repeal of 19 TAC §232.27 would further clarify certificate renewal and CPE requirements.

Current 19 TAC Chapter 232, General Certification Provisions, establishes the renewal requirements relating to types and classes of certificates issued, CPE, and national criminal history record information review.

The proposed rule actions would amend 19 TAC §§232.7, 232.9, 232.11, 232.13, 232.15, 232.17, 232.19, 232.21, and 232.23 and repeal 19 TAC §232.27. The proposed rule actions to 19 TAC Chapter 232 identify necessary changes based on recent legislation passed during the 84th Texas Legislature, Regular Session, 2015, and reflect input received from the SBEC and Texas Education Agency (TEA) staff-convened stakeholder meetings. The proposed rule actions also result from the SBEC's rule review of 19 TAC Chapter 232 conducted in accordance with Texas Government Code, §2001.039.

§232.7. Requirements for Certificate Renewal

Language would be amended to delete subsection (c) that requires licensure, certification, or registration to be current and in good standing before career and technical education (CTE) certificates can be renewed. TEA staff recommends this rule change to ensure no classroom certificate area is treated differently from others as it relates to certificate renewal requirements. Because current CPE requirements state that at least 80% of the hours should be directly related to the certificate(s) being renewed, TEA staff believes that CTE certificate holders can maintain focused training in their area(s) of certification and remain current in the knowledge and skills necessary to successfully deliver instruction and positively influence student learning. The remaining subsections would be relettered accordingly.

§232.9. Inactive Status and Late Renewal

Language would be amended in subsection (d) to require a person whose certificate has become inactive because of failure to renew to verify through an affidavit that the person is in compliance with renewal requirements. Proposed new subsection (e) would confirm TEA staff is responsible for completing audits of educator CPE hours. The auditing procedures would be dependent on the availability of TEA resources and may include random audits. TEA staff will be responsible for contacting educators directly and providing them with all information needed to submit required documentation for completion of certificate renewal audits. The language would also confirm that the TEA staff may require written documentation of all activities applied toward CPE requirements. Proposed new subsection (f) would confirm that a person who falsifies information submitted on an affidavit could be subject to criminal liability and educator certification sanction. These proposed changes would clarify the process to reactivate an inactive certificate as well as the process that TEA

staff would use to verify that the renewal requirements have been met.

§232.11. Number and Content of Required Continuing Professional Education Hours

Language would be amended in subsection (c) to clarify that at least 80% of the required CPE activities be directly related to the renewal of the certificate(s) being renewed and focus on the standards required for initial issuance of the certificate(s). As a result of SB 382, 84th Texas Legislature, Regular Session, 2015, proposed new subsection (h) would be added to allow an educator to receive credit towards CPE requirements by completing an instructional course on the use of an AED that meets specified AED training guidelines. Proposed new subsection (i) would allow educators to receive CPE credit for completing suicide prevention training that meets the guidelines in the TEC, §21.451, as amended by House Bill 2186, 84th Texas Legislature, Regular Session, 2015.

§232.13. Number of Required Continuing Professional Education Hours by Classes of Certificates

Language would be amended in subsections (c) and (d) to match current wording in subsections (e), (f), and (g) that clearly states the 200-clock hour CPE requirement. Language would also be amended in subsections (c) and (d) to reference the renewal requirements that are specific to the school counselor and school librarian certificates. These proposed changes would clarify and align the requirements for certification renewal.

§232.15. Types of Acceptable Continuing Professional Education Activities

Language would be amended in subsection (a)(1) and (3) to clarify that the activities need to be in the content area knowledge and skills related to the certificate(s) being renewed. This proposed change would align the types of acceptable CPE activities.

§232.17. Pre-Approved Professional Education Provider or Sponsor

Language would be amended in subsection (a)(5) to include Texas public open-enrollment charter schools to the list of pre-approved professional education providers or sponsors. This proposed change would allow certified educators employed by an open-enrollment charter school to receive CPE credit for acceptable CPE activities provided by their employer.

§232.19. Approval of Private Companies, Private Entities, and Individuals

Language would be amended to clarify that this section is only for private companies, private entities, and individuals who seek to provide CPE on their own behalf and not through the sponsorship of a pre-approved provider or sponsor.

§232.21. Provider Registration Requirements

Language would be amended in subsection (c) to require providers to maintain a record of CPE activity for a period of seven years after the activity. This proposed change would assist TEA staff in confirming CPE credits when auditing an educator's renewal requirements. Language would be amended in subsection (d) to clarify that the withdrawal of approval to provide CPE does not entitle a provider or sponsor to a contested-case hearing before the SBEC. Proposed new subsection (f) would allow TEA staff to review the documentation that is required for provider or sponsor approval. If TEA staff determines that a provider or sponsor is operating in violation

of applicable laws or rules, the TEA staff may withdraw the approval that had been granted.

§232.23. Verification of Renewal Requirements

Current subsection (c) would be replaced to confirm TEA staff is responsible for completing audits of educator CPE hours. The auditing procedures would be dependent on the availability of TEA resources and may include random audits. TEA staff would be responsible for contacting educators directly and providing them with all information needed to submit required documentation for completion of certificate renewal audits. The language would also confirm that the TEA staff may require written documentation of all activities applied toward CPE requirements. Language in subsection (b) would be moved to proposed new subsection (d).

The proposed amendments and repeal would have no reporting requirements; however, there would be procedural implications. The proposed amendments to 19 TAC §232.9 and §232.23 would clarify that an educator must provide TEA staff with documentation if an educator's certification renewal record is selected for an audit. The documentation may include the documentation described in §232.15, Types of Acceptable Continuing Professional Education Activities, and §232.21, Provider Registration Requirements, but at the minimum, it would include a summary CPE worksheet. The proposed amendments and repeal would clarify locally maintained paperwork requirements for CPE providers. The proposed amendment to 19 TAC §232.21 does not change the documentation requirements for what CPE providers need to maintain regarding CPE activity, but would add a seven-year retention period requirement for CPE providers after a CPE activity is provided. The proposed amendment to 19 TAC §232.21 would clarify that TEA staff may review the documentation required for CPE provider registration.

FISCAL NOTE. Ryan Franklin, associate commissioner for educator leadership and quality, has determined that for the first five-year period the proposed amendments and repeal are in effect there will be no additional fiscal implications for state or local government as a result of enforcing or administering the proposed amendments and repeal.

PUBLIC BENEFIT/COST NOTE. Mr. Franklin has determined that for the first five-year period the proposed amendments and repeal are in effect the public and student benefit anticipated as a result of the proposed amendments and repeal would be clarified certificate renewal requirements relating to the types and classes of certificates issued. There are no additional costs to persons required to comply with the proposed amendments and repeal.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND MICROBUSINESSES. There is no direct adverse economic impact for small businesses and microbusinesses; therefore, no regulatory flexibility analysis, specified in Texas Government Code, §2006.002, is required.

REQUEST FOR PUBLIC COMMENT. The public comment period on the proposal begins March 11, 2016, and ends April 11, 2016. The SBEC will take registered oral and written comments on the proposed revisions to 19 TAC Chapter 232 at the April 15, 2016 meeting in accordance with the SBEC board operating policies and procedures. Comments on the proposal may be submitted to Cristina De La Fuente-Valadez, Rulemaking, Texas Education Agency, 1701 North Congress Avenue, Austin, Texas 78701, (512) 475-1497. Comments may also be submitted electronically to sbecrules@tea.texas.gov or faxed to (512)

463-5337. All requests for a public hearing on the proposed amendments and repeal submitted under the Administrative Procedure Act must be received by the Department of Educator Leadership and Quality, Texas Education Agency, 1701 North Congress Avenue, Austin, Texas 78701, Attention: Mr. Ryan Franklin, associate commissioner for educator leadership and quality, not more than 14 calendar days after notice of the proposal has been published in the *Texas Register* on March 11, 2016.

19 TAC §§232.7, 232.9, 232.11, 232.13, 232.15, 232.17, 232.19, 232.21, 232.23

STATUTORY AUTHORITY. The amendments are proposed under the Texas Education Code (TEC), §21.003(a), which states that a person may not be employed as a teacher, teacher intern or teacher trainee, librarian, educational aide, administrator, educational diagnostician, or school counselor by a school district unless the person holds an appropriate certificate or permit issued as provided by the TEC, Chapter 21, Subchapter B; §21.0031(f), which clarifies and places certain limits on provisions authorizing termination of an educator's contract for failure to maintain a valid certificate; §21.031(a), which states that the State Board for Educator Certification (SBEC) shall regulate and oversee all aspects of the certification, continuing education, and standards of conduct of public school educators; §21.031(b), which states that in proposing rules under the TEC, Chapter 21, Subchapter B, the SBEC shall ensure that all candidates for certification or renewal of certification demonstrate the knowledge and skills necessary to improve the performance of the diverse student population of this state; §21.041(b)(1), which requires the SBEC to propose rules that provide for the regulation of educators and the general administration of the TEC, Chapter 21, Subchapter B, in a manner consistent with the TEC, Chapter 21, Subchapter B; §21.041(b)(2), which requires the SBEC to propose rules that specify the classes of educator certificates to be issued, including emergency certificates; §21.041(b)(3), which requires the SBEC to propose rules that specify the period for which each class of educator certificate is valid; §21.041(b)(4), which requires the SBEC to propose rules that specify the requirements for the issuance and renewal of an educator certificate; §21.041(b)(7), which requires the SBEC to propose rules that provide for disciplinary proceedings, including the suspension or revocation of an educator certificate, as provided by the Texas Government Code, Chapter 2001; §21.041(b)(8), which requires the SBEC to propose rules that provide for the enforcement of an educator's code of ethics; §21.041(b)(9), which requires the SBEC to propose rules that provide for continuing education requirements; §21.054, which requires classroom teachers, principals, and school counselors to earn continuing professional education units in specific areas and options for meeting those requirements and directs the SBEC to propose rules relating to continuing education courses and programs for educators; and §21.0541, as added by Senate Bill (SB) 382, 84th Texas Legislature, Regular Session, 2015, which requires the SBEC to adopt rules that allow an educator to receive credit towards the educator's continuing education requirements for completion of an instructional course on the use of an automated external defibrillator that meets the guidelines for automated external defibrillator training approved under the Texas Health and Safety Code, §779.002; and the Texas Occupations Code (TOC), §55.002, as amended by SB 1307, 84th Texas Legislature, Regular Session, 2015, which exempts a military service member from increased fees or penalties resulting from failing to timely renew a license; and §55.003, as amended

by SB 1307, 84th Texas Legislature, Regular Session, 2015, which grants an extension of two years of additional time to complete license renewal and continuing education requirements to a military service member.

CROSS REFERENCE TO STATUTE. The proposed amendments implement the TEC, §§21.003(a), 21.0031(f), 21.031, 21.041(b)(1)-(4) and (7)-(9), 21.054; and 21.0541, as added by SB 382, 84th Texas Legislature, Regular Session, 2015; and the TOC, §55.002, as amended by SB 1307, 84th Texas Legislature, Regular Session, 2015; and §55.003, as amended by SB 1307, 84th Texas Legislature, Regular Session, 2015.

§232.7. Requirements for Certificate Renewal.

(a) The Texas Education Agency (TEA) staff shall develop procedures to:

(1) notify educators at least six months prior to the expiration of the renewal period to the email address as specified in §230.91 of this title (relating to Procedures in General);

(2) consider requests for hardship when circumstances beyond the control of the educator such as catastrophic illness of the educator or an immediate family member or military service of the educator prevented completion of the renewal requirements. If a hardship exemption is granted, the educator will be given a designated amount of time to complete the required number of continuing professional education clock-hours, apply, and pay the appropriate fee. The granting or denial of a request for extension of a renewal deadline shall be solely within the discretion of TEA staff and shall not be subject to appeal;

(3) confirm compliance with all renewal requirements pursuant to this subchapter;

(4) notify educators who are not renewed due to noncompliance with this section; and

(5) verify that educators applying for reactivation of certificate(s) under §232.9 of this title (relating to Inactive Status and Late Renewal) are in compliance with subsection (b)(2)-(6) of this section.

(b) To be eligible for renewal, an educator must:

(1) satisfy continuing professional education requirements, pursuant to §232.11 of this title (relating to Number and Content of Required Continuing Professional Education Hours);

(2) hold a valid standard certificate that is not currently suspended and has not been surrendered in lieu of revocation or revoked by lawful authority;

(3) not be a respondent in a disciplinary proceeding under Chapter 249 of this title (relating to Disciplinary Proceedings, Sanctions, and Contested Cases);

(4) successfully resolve any reported criminal history, as defined by §249.3 of this title (relating to Definitions);

(5) not be in default on a guaranteed student loan reported by the Texas Guaranteed Student Loan Corporation or a judgment debt for a student loan owed to the Texas Higher Education Coordinating Board, unless repayment arrangements have been made;

(6) not be in arrears of child support, pursuant to the Texas Family Code, Chapter 232;

(7) pay the renewal fee, pursuant to §232.25 of this title (relating to Fees Payable Upon Certificate Renewal or Reactivation), which shall be a single fee regardless of the number of certificates being renewed; and

(8) submit fingerprints in accordance with §232.35(c) of this title (relating to Submission of Required Information) and the TEC, §22.0831.

~~[(c) When renewing career and technical education certifications that require licensure, certification, or registration by a state or nationally recognized accrediting agency as a professional practitioner in one or more approved occupations for which instruction is offered, licensure, certification, or registration shall be current and in good standing.]~~

~~(c) [(d)]~~ The TEA staff shall renew the certificate(s) of an educator who meets all requirements of this subchapter.

~~(d) [(e)]~~ The State Board for Educator Certification shall stay the renewal of an educator's certificate(s) who fails to comply with subsection (b)(3) of this section, pending resolution of the disciplinary action. A certificate that is not suspended, surrendered in lieu of revocation, or revoked shall be renewed upon the final resolution of the disciplinary action provided that all other requirements have been satisfied. The renewal of a suspended certificate shall be stayed until the certificate has been reinstated. Payment of a late fee shall not be required if the late renewal is solely due to the pendency of a disciplinary action or to a suspension.

§232.9. Inactive Status and Late Renewal.

(a) The certificate(s) of an educator holding a valid standard certificate who does not satisfy the requirements of this subchapter shall be placed on inactive status, subject to the requirements of the Texas Education Code, §21.0031(f). At any time, the educator may apply under procedures adopted by the Texas Education Agency (TEA) staff to have his or her certificate(s) reactivated and submit the reactivation fee. Reactivation of the educator's certificate(s) is subject to verification by the State Board for Educator Certification (SBEC) that the educator is in compliance with §232.7 of this title (relating to Requirements for Certificate Renewal). The renewal date of a reactivated certificate(s) shall be five years after the last day of the certificate holder's next birth month.

(b) Under procedures approved by the SBEC, the TEA staff shall notify a person by email of the reason(s) for denying the renewal and the actions or conditions required for removal from inactive status.

(c) A person who satisfies all requirements for renewal after the renewal date of a certificate shall pay a late renewal fee in addition to the standard renewal fee. A person whose certificate has become inactive because of failure to renew shall also pay a reactivation fee. The amount of these fees shall be as provided in §230.101 of this title (relating to Schedule of Fees for Certification Services).

(d) If a person does not satisfy the required continuing professional education (CPE) hours at the expiration of the renewal period, the person may have the certificate(s) removed from inactive status and reactivated by verifying through an affidavit in a manner determined by the TEA staff whether he or she is in compliance with renewal requirements, including CPE hours, [filing with the SBEC, on a form developed by the TEA staff, evidence of completion of the required CPE hours] and paying any applicable fee(s).

(e) The TEA staff shall be responsible for auditing compliance with renewal requirements. The TEA audit procedures shall be based on available resources and may include random audits. The TEA staff shall contact an educator selected for an audit of his or her renewal requirements and provide the educator with information needed to submit the documentation that supports certificate renewal. The TEA staff at any time may review the documentation required for renewal under this subchapter, which may include the documentation described in §232.15 of this title (relating to Types of Acceptable Continuing

Professional Education Activities) and §232.21 of this title (relating to Provider Registration Requirements).

(f) If it is determined that a person falsified any information submitted on the affidavit, the person could be subject to criminal liability and educator certification sanction.

§232.11. Number and Content of Required Continuing Professional Education Hours.

(a) The appropriate number of clock-hours of continuing professional education (CPE), as specified in §232.13 of this title (relating to Number of Required Continuing Professional Education Hours by Classes of Certificates), must be completed during each five-year renewal period.

(b) One semester credit hour earned at an accredited institution of higher education is equivalent to 15 CPE clock-hours.

(c) At least 80% of the CPE activities shall ~~shall~~ should be directly related to the certificate(s) being renewed and focus on the standards required for the initial issuance of the certificate(s), including:

(1) content area knowledge and skills;

(2) professional ethics and standards of conduct;

(3) professional development, which should encompass topics such as the following:

(A) district and campus priorities and objectives;

(B) child development, including research on how children learn;

(C) classroom management;

(D) applicable federal and state laws;

(E) diversity and special needs of student populations;

(F) increasing and maintaining parental involvement;

(G) integration of technology into educational practices;

(H) ensuring that students read on or above grade level;

(I) diagnosing and removing obstacles to student achievement; and

(J) instructional practices.

(4) Not more than 25% of the CPE activities for a classroom teacher shall include instruction regarding:

(A) collecting and analyzing information that will improve effectiveness in the classroom;

(B) recognizing early warning indicators that a student may be at risk of dropping out of school;

(C) integrating technology into classroom instruction; and

(D) educating diverse student populations, including:

(i) students with disabilities, including mental health disorders;

(ii) students who are educationally disadvantaged;

(iii) students of limited English proficiency; and

(iv) students at risk of dropping out of school.

(5) Not more than 25% of the CPE activities for a principal shall include instruction regarding:

(A) effective and efficient management, including:
(i) collecting and analyzing information;
(ii) making decisions and managing time; and
(iii) supervising student discipline and managing behavior;

(B) recognizing early warning indicators that a student may be at risk of dropping out of school;

(C) integrating technology into campus curriculum and instruction; and

(D) educating diverse student populations, including:
(i) students with disabilities, including mental health disorders;

(ii) students who are educationally disadvantaged;

(iii) students of limited English proficiency; and

(iv) students at risk of dropping out of school.

(6) Not more than 25% of the CPE activities for a school counselor shall include instruction regarding:

(A) assisting students in developing high school graduation plans;

(B) implementing dropout prevention strategies; and

(C) informing students concerning:

(i) college admissions, including college financial aid resources and application procedures; and

(ii) career opportunities.

(d) Educators are encouraged to identify CPE activities based on results of his or her annual appraisal required under the Texas Education Code, Chapter 21, Subchapter H.

(e) The required CPE for educators who teach students with dyslexia must include training regarding new research and practices in educating students with dyslexia. The required training may be satisfied through an online course approved by Texas Education Agency staff.

(f) An educator eligible to renew multiple classes of certificates issued during the same renewal period may satisfy the requirements specified in §232.13 of this title for any class of certificate issued for less than the full five-year period by completing a prorated number of the required CPE clock-hours. Educators must complete a minimum of one-fifth of the additional CPE clock-hours for each full calendar year that the additional class of certificate is valid.

(g) An educator may fulfill up to 12 clock-hours of required CPE activities by participating in a mental health first aid training program offered by a local mental health authority under the Texas Health and Safety Code, §1001.203. The number of clock-hours of CPE an educator may fulfill under this subsection may not exceed the number of clock-hours the educator actually spends participating in a mental health first aid training program.

(h) An educator may receive credit towards CPE requirements for completion of an instructional course on the use of an automated external defibrillator (AED) that meets the guidelines for AED training approved under Texas Health and Safety Code, §779.002, in accordance with the Texas Education Code (TEC), §21.0541.

(i) An educator may receive credit towards CPE requirements for completion of suicide prevention training that meets the guidelines for suicide prevention training approved under the TEC, §21.451.

§232.13. Number of Required Continuing Professional Education Hours by Classes of Certificates.

(a) Holders of the Standard Superintendent Certificate shall complete 200 clock-hours of continuing professional education (CPE) every five years. Specific requirements are contained in §242.30 of this title (relating to Requirements to Renew the Standard Superintendent Certificate).

(b) Holders of the Standard Principal Certificate shall complete 200 clock-hours of CPE every five years. Specific requirements are contained in §241.30 of this title (relating to Requirements to Renew the Standard Principal Certificate).

(c) Holders of the Standard School Counselor Certificate shall complete 200 clock-hours of CPE [training as specified in §239.25(a) of this title (relating to Requirements to Renew the Standard School Counselor Certificate)] every five years. Specific requirements are contained in §239.25 of this title (relating to Requirements to Renew the Standard School Counselor Certificate).

(d) Holders of the Standard School Librarian Certificate and Learning Resources Specialist Certificate shall complete 200 clock-hours of CPE [training as specified in §239.65(a) of this title (relating to Requirements to Renew the Standard School Librarian Certificate)] every five years. Specific requirements are contained in §239.65 of this title (relating to Requirements to Renew the Standard School Librarian Certificate).

(e) Holders of the Standard Educational Diagnostician Certificate shall complete 200 clock-hours of CPE every five years.

(f) Holders of the Standard Reading Specialist Certificate shall complete 200 clock-hours of CPE every five years.

(g) Holders of the Standard Master Teacher Certificate shall complete 200 clock-hours of CPE every five years.

(h) Holders of the Standard Classroom Teacher Certificate shall complete 150 clock-hours of CPE every five years. Specific requirements are contained in §232.11 of this title (relating to Number and Content of Required Continuing Professional Education Hours).

(i) Holders of the Standard Educational Aide Certificate are exempt from the provisions of §232.11 of this title.

(j) Holders of professional certificates issued prior to September 1, 1999, who opt into the Standard Certificate pursuant to §232.3 of this title (relating to Voluntary Renewal of Current Texas Educators) shall complete 200 clock-hours of CPE every five years.

(k) Holders of provisional certificates issued prior to September 1, 1999, who opt into the Standard Certificate pursuant to §232.3 of this title shall complete 150 clock-hours of CPE every five years.

(l) An educator holding multiple classes of certificates shall complete the higher number of required CPE clock-hours in the held classes during each five-year renewal period unless otherwise specified in applicable State Board for Educator Certification rules codified in the Texas Administrative Code, Title 19, Part 7.

(m) Holders of a Standard Certificate in other professional areas must complete 200 clock-hours of CPE every five years.

§232.15. Types of Acceptable Continuing Professional Education Activities.

(a) The following are acceptable types of continuing professional education (CPE) activities:

(1) participating in institutes, workshops, seminars, conferences, interactive distance learning, video conferencing, online activities, and in-service or staff development activities given by an approved provider or sponsor, pursuant to §232.21 of this title (relating to Provider Registration Requirements), in content area knowledge and skills related to the certificate(s) being renewed [which are related to or enhance the professional knowledge and skills of the educator]. Staff development activities completed through accredited public and private schools in other states, United States territories, and countries other than the United States may be accepted;

(2) completing undergraduate courses in content area knowledge and skills related to the certificate(s) being renewed, graduate courses, or training programs that are taken through an accredited institution of higher education that at the time was accredited or otherwise approved by an accrediting organization recognized by the Texas Higher Education Coordinating Board or as outlined in §230.1 of this title (relating to Definitions);

(3) participating in an independent study in content area knowledge and skills related to the certificate(s) being renewed, not to exceed 20% of the required clock-hours, which may include:

(A) self-study of relevant professional materials (e.g., books, journals, periodicals, video and audio tapes, computer software, interactive distance learning, video conferencing, or online activities);

(B) developing curriculum; or

(C) authoring a published work;

(4) developing, teaching, or presenting a CPE activity described in this subsection or subsection (b) of this section, not to exceed 10% of the required clock-hours; and

(5) providing professional guidance as a mentor to another educator, not to exceed 30% of the required clock-hours.

(b) Completion of each CPE activity should be evidenced by documentation (e.g., transcripts, certificates of completion, or attendance logs).

§232.17. Pre-Approved Professional Education Provider or Sponsor.

(a) The following may provide and/or sponsor continuing professional education (CPE) activities and must comply with the provisions of §232.21 of this title (relating to Provider Registration Requirements). Pre-approved providers include:

(1) State Board for Educator Certification;

(2) Texas Education Agency;

(3) accredited institutions of higher education that at the time were accredited or otherwise approved by an accrediting organization recognized by the Texas Higher Education Coordinating Board;

(4) regional education service centers;

(5) Texas public school districts and open-enrollment charter schools. To be creditable toward CPE requirements, school district in-service and/or staff development activities must be developed, approved, and conducted in accordance with the Texas Education Code, §21.451;

(6) private schools, as defined in §230.1 of this title (relating to Definitions); and

(7) professional membership associations or non-profits that have offered professional development in Texas for at least five years and have tax-exempt status under 26 United States Code, §501(c)(3)-(6), or a state association affiliated with a national association with tax-exempt status.

(b) If private companies, entities, and individuals provide CPE activities on behalf of a pre-approved provider, the pre-approved provider is responsible for ensuring compliance with quality and documentation requirements of §232.21 of this title.

§232.19. Approval of Private Companies, Private Entities, and Individuals.

Private companies, private entities, and individuals who wish to provide continuing professional education (CPE) for Texas educators on their own behalf [and administrators] must register with the State Board for Educator Certification and be approved under §232.21 of this title (relating to Provider Registration Requirements).

(1) The Texas Education Agency staff shall develop procedures to approve as providers and/or sponsors any other person, agency, or entity seeking to offer CPE activities pursuant to the requirements of this subchapter.

(2) It is the responsibility of the educator to verify the approval status of any CPE provider prior to completion of the CPE activities.

§232.21. Provider Registration Requirements.

(a) Procedures adopted by the Texas Education Agency (TEA) staff require all pre-approved and all other continuing professional education (CPE) providers or sponsors to register with the State Board for Educator Certification (SBEC) by submitting the relevant sections of the provider registration form designated by the TEA staff in order to accomplish any or all of the following, as applicable:

(1) notify the TEA staff of the intent to offer CPE activities;

(2) affirm compliance with all applicable statutes and rules;

(3) prohibit discrimination in the provision of CPE activities to any certified educator;

(4) document that each CPE activity:

(A) complies with applicable SBEC rules codified in the Texas Administrative Code, Title 19, Part 7;

(B) contributes to the advancement of professional knowledge and skills identified by standards adopted by the SBEC for each certificate;

(C) is developed and presented by persons who are appropriately knowledgeable in the subject matter of the training being offered; and

(D) specifies the content under §232.11 of this title (relating to Number and Content of Required Continuing Professional Education Hours) and number of creditable CPE clock-hours; and

(5) on a biennial or more frequent basis, conduct a comprehensive, in-depth self-study to assess the CPE needs and priorities of educators served by the provider as well as the quality of the CPE activities offered.

(b) At the conclusion of each activity offered for CPE credit, the provider or sponsor must provide to each educator in attendance written documentation listing, at a minimum, the provider's name and provider number, the educator's name, the date and content of the activity, and the number of clock-hours that count toward satisfying CPE requirements.

(c) All providers are required to maintain a record [list] of CPE activities [provided] that includes a list of attendees, the date and content of the activity, and the number of clock-hours that count toward satisfying CPE requirements. Providers shall retain a record of CPE activity for a period of seven years after the activity is completed.

(d) A [The failure of the TEA staff to approve a] provider or sponsor that is not granted approval or has its approval withdrawn by the TEA staff is [does] not entitled [entitle that provider or sponsor] to a contested-case hearing before the SBEC or a person designated by the SBEC to conduct contested-case hearings.

(e) The TEA staff shall develop procedures to receive and investigate complaints against a provider or sponsor alleging noncompliance with this section. If the investigation determines that the provider or sponsor is operating in violation of any applicable provision of state law or rule, the TEA staff may withdraw the approval granted under this section to the provider or sponsor.

(f) The TEA staff at any time may review the documentation required for provider registration under this section. If TEA staff determines that the provider or sponsor is operating in violation of any applicable provision of state law or rule, the TEA staff may withdraw the approval granted under this section to the provider or sponsor.

§232.23. *Verification of Renewal Requirements.*

(a) Written documentation of completion of all activities applied toward continuing professional education (CPE) requirements shall be maintained by each educator.

(b) By the date renewal is required, the educator shall verify through an affidavit in a manner determined by the Texas Education Agency (TEA) staff whether he or she is in compliance with renewal requirements, including CPE. ~~[If it is determined that an educator falsified any information submitted on the affidavit, the educator could be subject to criminal liability and educator certification sanction.]~~

(c) The TEA staff shall be responsible for auditing compliance with renewal requirements. The TEA audit procedures shall be based on available resources and may include random audits. The TEA staff shall contact an educator selected for an audit of his or her renewal requirements and provide the educator with information needed to submit the documentation that supports certificate renewal. The TEA staff at any time may review the documentation required for renewal under this subchapter, which may include the documentation described in §232.15 of this title (relating to Types of Acceptable Continuing Professional Education Activities) and §232.21 of this title (relating to Provider Registration Requirements).

(d) If it is determined that an educator falsified any information submitted on the affidavit, the educator could be subject to criminal liability and educator certification sanction.

~~[(e) The TEA staff at any time may review the documentation required for renewal under this subchapter.]~~

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 29, 2016.

TRD-201601007

Cristina De La Fuente-Valadez

Director, Rulemaking, Texas Education Agency

State Board for Educator Certification

Earliest possible date of adoption: April 10, 2016

For further information, please call: (512) 475-1497



19 TAC §232.27

STATUTORY AUTHORITY. The repeal is proposed under the Texas Education Code (TEC), §21.003(a), which states that a person may not be employed as a teacher, teacher intern or teacher trainee, librarian, educational aide, administrator, educational diagnostician, or school counselor by a school district unless the person holds an appropriate certificate or permit issued as provided by the TEC, Chapter 21, Subchapter B; §21.0031(f), which clarifies and places certain limits on provisions authorizing termination of an educator's contract for failure to maintain a valid certificate; §21.031(a), which states that the State Board for Educator Certification (SBEC) shall regulate and oversee all aspects of the certification, continuing education, and standards of conduct of public school educators; §21.031(b), which states that in proposing rules under the TEC, Chapter 21, Subchapter B, the SBEC shall ensure that all candidates for certification or renewal of certification demonstrate the knowledge and skills necessary to improve the performance of the diverse student population of this state; §21.041(b)(1), which requires the SBEC to propose rules that provide for the regulation of educators and the general administration of the TEC, Chapter 21, Subchapter B, in a manner consistent with the TEC, Chapter 21, Subchapter B; §21.041(b)(2), which requires the SBEC to propose rules that specify the classes of educator certificates to be issued, including emergency certificates; §21.041(b)(3), which requires the SBEC to propose rules that specify the period for which each class of educator certificate is valid; §21.041(b)(4), which requires the SBEC to propose rules that specify the requirements for the issuance and renewal of an educator certificate; §21.041(b)(7), which requires the SBEC to propose rules that provide for disciplinary proceedings, including the suspension or revocation of an educator certificate, as provided by the Texas Government Code, Chapter 2001; §21.041(b)(8), which requires the SBEC to propose rules that provide for the enforcement of an educator's code of ethics; §21.041(b)(9), which requires the SBEC to propose rules that provide for continuing education requirements; §21.054, which requires classroom teachers, principals, and school counselors to earn continuing professional education units in specific areas and options for meeting those requirements and directs the SBEC to propose rules relating to continuing education courses and programs for educators; and §21.0541, as added by Senate Bill (SB) 382, 84th Texas Legislature, Regular Session, 2015, which requires the SBEC to adopt rules that allow an educator to receive credit towards the educator's continuing education requirements for completion of an instructional course on the use of an automated external defibrillator that meets the guidelines for automated external defibrillator training approved under the Texas Health and Safety Code, §779.002; and the Texas Occupations Code (TOC), §55.002, as amended by SB 1307, 84th Texas Legislature, Regular Session, 2015, which exempts a military service member from increased fees or penalties resulting from failing to timely renew a license; and §55.003, as amended by SB 1307, 84th Texas Legislature, Regular Session, 2015, which grants an extension of two years of additional time to complete license renewal and continuing education requirements to a military service member.

CROSS REFERENCE TO STATUTE. The proposed repeal implements the TEC, §§21.003(a), 21.0031(f), 21.031, 21.041(b)(1)-(4) and (7)-(9), 21.054; and 21.0541, as added by SB 382, 84th Texas Legislature, Regular Session, 2015; and the TOC, §55.002, as amended by SB 1307, 84th Texas Legislature, Regular Session, 2015; and §55.003, as amended by SB 1307, 84th Texas Legislature, Regular Session, 2015.

§232.27. *Renewal and Continuing Education Requirements for Military Service Members.*

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 29, 2016.

TRD-201601008

Cristina De La Fuente-Valadez

Director, Rulemaking, Texas Education Agency

State Board for Educator Certification

Earliest possible date of adoption: April 10, 2016

For further information, please call: (512) 475-1497



CHAPTER 234. MILITARY SERVICE MEMBERS, MILITARY SPOUSES, AND MILITARY VETERANS

19 TAC §§234.1, 234.3, 234.5, 234.7

The State Board for Educator Certification (SBEC) proposes new 19 TAC §§234.1, 234.3, 234.5, and 234.7, concerning requirements for military service members, military spouses, and military veterans. The sections establish requirements for the certification of a military service member, military veteran, or military spouse and the renewal and continuing education requirements for military service members. Proposed new 19 TAC §§234.1, 234.3, 234.5, and 234.7 would address recent legislation, consolidate rules specific to the military community into one chapter, and streamline future military-related rulemaking opportunities.

The 84th Texas Legislature, Regular Session, 2015, passed Senate Bill (SB) 807, which requires all state licensing agencies to adopt rules that implement the requirements of the Texas Occupations Code (TOC), Chapter 55, regarding the licensing of military service members, military spouses, and military veterans and the waiving of licensing and application fees paid to the state. The 84th Texas Legislature also passed SB 1307, which clarifies definitions of military spouses and military veterans in key sections of the TOC, allows for the adoption of rules to establish alternative methods for military groups to meet requirements for licensure, grants the executive director of a state agency to review applicant credentials and waive requirements for licensure, and incorporates the use of verified military service to satisfy apprenticeship requirements for licensure.

In addition, the 84th Texas Legislature passed House Bill 2014, which allows military service members seeking certification in career and technical education to substitute experience in a particular trade for the license or professional credential in the specific trade.

Proposed new 19 TAC Chapter 234 would consolidate all military-related provisions into one chapter. The military-related provisions currently outlined in 19 TAC §230.15, Certification of Military Service Members, Military Spouses, and Military Veterans, and 19 TAC §232.27, Renewal and Continuing Education Requirements for Military Service Members, would be repealed as applicable from 19 TAC Chapter 230 and 19 TAC Chapter 232. These provisions would be incorporated into the new military chapter as proposed new 19 TAC §234.5 and 19 TAC §234.7,

respectively. Proposed new 19 TAC §234.5(g) and (h) would satisfy the provisions in SB 807 and align with current SBEC rules.

Proposed new 19 TAC Chapter 234 would also streamline future military-related rulemaking opportunities by having all military-related provisions in one chapter.

The proposed rule actions would have no procedural and reporting implications. Also, the proposed rule actions would have no locally maintained paperwork requirements.

FISCAL NOTE. Ryan Franklin, associate commissioner for educator leadership and quality, has determined that for the first five-year period the proposed new sections are in effect there will be fiscal implications for state government as a result of enforcing or administering the proposed new sections.

The estimated cost to the state (TEA) begins with Fiscal Year (FY) 2016 based on the September 1, 2015 effective date of SB 807, 84th Texas Legislature, Regular Session, 2015. Based on current tracking of legislation effective September 1, 2015, the TEA estimates the number of individuals that would apply for certification at 500 for FY 2016, 550 for FY 2017, 605 for FY 2018, 665 for FY 2019, and 731 for FY 2020. The TEA estimates that approximately 75% would apply through the out-of-state route to certification while 25% would apply through the educator preparation program (EPP) route to certification.

For the TEA, the total estimated cost would be \$143,500 for FY 2016, \$157,940 for FY 2017, \$173,500 for FY 2018, \$190,720 for FY 2019, and \$209,752 for FY 2020. The total estimated cost for each year of FY 2016-FY 2020 is based on fees for the out-of-state route to certification (test fees of \$22, credential review fee of \$180, and certificate issuance fees of \$52 and \$78) and the EPP route to certification (test fees of \$22 and certificate issuance fees of \$52 and \$78).

For the TEA, the estimated loss in revenue would be \$143,500 for FY 2016, \$157,940 for FY 2017, \$173,500 for FY 2018, \$190,720 for FY 2019, and \$209,752 for FY 2020. This estimate is based on the fees that the TEA would not be collecting.

The TEA staff has determined that there is no additional fiscal impact on local government as a result of enforcing or administering the proposed new sections.

There is an anticipated economic savings to persons who are required to comply with the proposed new sections. For individuals (military service members, military spouses, and military veterans) not required under SB 807 to pay certification fees, the total estimated savings would be approximately \$143,500 for FY 2016, \$157,940 for FY 2017, \$173,500 for FY 2018, \$190,720 for FY 2019, and \$209,752 for FY 2020. Based on current fees an individual would save \$152 or \$332 depending on the route to certification.

PUBLIC BENEFIT/COST NOTE. Mr. Franklin has determined that for the first five-year period the proposed new sections are in effect the public and student benefit anticipated as a result of the proposed new sections would be implementing statutory provisions for expediting and facilitating the educator certification of military service members, military spouses, and military veterans. The anticipated economic cost to persons who are required to comply with the proposed new sections is described earlier under Fiscal Note.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND MICROBUSINESSES. There is no direct adverse economic

impact for small businesses and microbusinesses; therefore, no regulatory flexibility analysis, specified in Texas Government Code, §2006.002, is required.

REQUEST FOR PUBLIC COMMENT. The public comment period on the proposal begins March 11, 2016, and ends April 11, 2016. The SBEC will take registered oral and written comments on proposed new 19 TAC Chapter 234 at the April 15, 2016 meeting in accordance with the SBEC board operating policies and procedures. Comments on the proposal may be submitted to Cristina De La Fuente-Valadez, Rulemaking, Texas Education Agency, 1701 North Congress Avenue, Austin, Texas 78701, (512) 475-1497. Comments may also be submitted electronically to sbecrules@tea.texas.gov or faxed to (512) 463-5337. All requests for a public hearing on the proposed new sections submitted under the Administrative Procedure Act must be received by the Department of Educator Leadership and Quality, Texas Education Agency, 1701 North Congress Avenue, Austin, Texas 78701, Attention: Mr. Ryan Franklin, associate commissioner for educator leadership and quality, not more than 14 calendar days after notice of the proposal has been published in the *Texas Register* on March 11, 2016.

STATUTORY AUTHORITY. The new sections are proposed under the Texas Education Code (TEC), §21.041(b)(2), which requires the State Board for Educator Certification (SBEC) to propose rules that specify the classes of educator certificates to be issued, including emergency certificates; §21.041(b)(4), which requires the SBEC to propose rules that specify the requirements for the issuance and renewal of an educator certificate; §21.044(a), which requires the SBEC to propose rules establishing training requirements a person must accomplish to obtain a certificate, enter an internship, or enter an induction-year program; and §21.054, which requires classroom teachers, principals, and school counselors to earn continuing professional education units in specific areas and options for meeting those requirements and directs the SBEC to propose rules relating to continuing education courses and programs for educators; and the Texas Occupations Code (TOC), §55.001, as amended by Senate Bill (SB) 1307, 84th Texas Legislature, Regular Session, 2015, which defines *active duty*, *armed forces of the United States*, *license*, *military service member*, *military spouse*, *military veteran*, and *state agency*; §55.002, as amended by SB 1307, 84th Texas Legislature, Regular Session, 2015, which exempts a military service member from increased fees or penalties resulting from failing to timely renew a license; §55.003, as amended by SB 1307, 84th Texas Legislature, Regular Session, 2015, which grants an extension of two years of additional time to complete license renewal and continuing education requirements to a military service member; §55.004, as amended by SB 1307 and House Bill (HB) 3742, 84th Texas Legislature, Regular Session, 2015, which provides an alternative licensing procedure for military service members, military veterans, and military spouses; §55.005, as amended by SB 1307, 84th Texas Legislature, Regular Session, 2015, which provides an expedited licensing procedure for military service members, military veterans, and military spouses; §55.006, as amended by SB 1307, 84th Texas Legislature, Regular Session, 2015, which provides for renewal of an expedited license issued to a military service member, military veteran, or military spouse; §55.007, which provides that verified military service, training, and education be credited toward licensing requirements; §55.008, as amended by SB 1296 and SB 1307, 84th Texas Legislature, Regular Session, 2015, which requires state agencies to credit military service, training or education toward apprenticeship requirements

for applicants with military experience; and §55.009, as added by SB 807 and SB 1307, 84th Texas Legislature, Regular Session, 2015, which waives the license application and examination fees for certain military service members, military veterans, and military spouses and requires a state agency that issues a license to prominently post a notice of the provisions in the TOC, Chapter 55, that are available to military service members, military veterans, and military spouses on the home page of the agency's website.

CROSS REFERENCE TO STATUTE. The proposed new sections implement the TEC, §§21.041(b)(2) and (4); 21.044(a); and 21.054; and Texas Occupations Code, §§55.001-55.003, 55.005, and 55.006, as amended by SB 1307, 84th Texas Legislature, Regular Session, 2015; 55.004, as amended by SB 1307 and HB 3742, 84th Texas Legislature, Regular Session, 2015; 55.007; 55.008, as amended by SB 1296 and SB 1307, 84th Texas Legislature, Regular Session, 2015; and 55.009, as added by SB 807 and SB 1307, 84th Texas Legislature, Regular Session, 2015.

§234.1. Purpose.

(a) The purpose of identifying military service members, military spouses, and military veterans is to establish a process to count applicable military service for timely admission into educator preparation programs, expedite the completion of certification credential reviews, support certification examination and licensure application fee exemptions as applicable, and support certification renewal of members of the military community.

(b) In the event of conflict with any other rule in the Texas Administrative Code, Title 19, Part 7, this chapter shall supersede with regard to the certification of military service members, military spouses, and military veterans.

§234.3. Definitions.

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

(1) Military service member--A person who is on active duty.

(2) Military spouse--A person who is married to a military service member.

(3) Military veteran--A person who has served on active duty and who was discharged or released from active duty.

(4) Active duty--Current full-time military service in the armed forces of the United States or active duty military service as a member of the Texas military forces, as defined by the Texas Government Code, §437.001, or similar military service of another state.

(5) Armed forces of the United States--The army, navy, air force, coast guard, or marine corps of the United States or a reserve unit of one of those branches of the armed forces.

§234.5. Certification of Military Service Members, Military Spouses, and Military Veterans.

(a) The application for certification of a military service member, military veteran, or military spouse, including an application based upon certification by a jurisdiction other than Texas that has certification requirements substantially similar to the Texas certification requirements, shall be processed as soon as practicable.

(b) As soon as practicable after the issuance of a one-year certificate, Texas Education Agency (TEA) staff shall notify, in writing or by email, a military spouse of the requirements for obtaining a standard Texas certificate. A military spouse whose active duty spouse has

been reassigned to another state during the validity period of the first one-year certificate would be eligible for a second one-year certificate.

(c) The standard Texas certificate of a military service member, military spouse, or military veteran may be renewed if that certificate has expired within five years preceding the Texas application date.

(d) A military service member or a military veteran shall be entitled to credit verified military service, training, or education toward the training, education, work experience, or related requirements (other than certification examinations) for educator certification. TEA staff and educator preparation programs (EPPs) shall use information from the U.S. Department of Veterans Affairs or other reliable sources to assist in crediting applicable military service, training, or education to certification requirements.

(e) A military service member pursuing certification in career and technical education must meet requirements for the certificate, but for career and technical education certificate areas requiring experience and licensure, the military service member shall be entitled to substitute military experience in the trade for the required license or professional credential for the specific trade.

(f) A military service member, military spouse, and military veteran shall complete educator examination requirements for certificate issuance as outlined in Texas Education Code, Chapter 21, Subchapter B, and rules in the Texas Administrative Code, Title 19, Part 7.

(g) Military service members and military veterans are exempt from certification application fees that are paid to the state that lead to initial certification. These members of the military community are exempt from paying the portion of the examination registration fee that is paid to the TEA.

(h) Military service members, military spouses, and military veterans are exempt from certification application fees that are paid to the state that lead to initial certification resulting from a review of credentials, one-year certificate, or out-of-state standard certificate. These members of the military community are exempt from paying the portion of the examination registration fee that is paid to the TEA.

§234.7. *Renewal and Continuing Education Requirements for Military Service Members.*

(a) A military service member shall be exempted from any fee or penalty for failing to timely renew his or her Texas educator certificate if the delay occurred because the educator was serving as a military service member.

(b) A military service member is entitled to two years of additional time to complete all continuing education requirements and any other requirements relating to the renewal of his or her Texas educator certificate.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 29, 2016.

TRD-201601009

Cristina De La Fuente-Valadez

Director, Rulemaking, Texas Education Agency

State Board for Educator Certification

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For further information, please call: (512) 475-1497



CHAPTER 241. PRINCIPAL CERTIFICATE

The State Board for Educator Certification (SBEC) proposes the repeal of 19 TAC §241.15 and new 19 TAC §241.15, concerning the principal certificate. The section provides standards required for the principal certificate. The proposed new section would update the standards required for principal certification, including those standards taught by principal preparation programs and tested on the state certification examination, and align the standards with the commissioner of education's principal appraisal standards.

In December 2014, Texas Education Agency (TEA) staff held a stakeholder meeting to discuss the rules in 19 TAC Chapter 241 as part of the rule review process. During the review process, the stakeholder group determined that the principal certificate standards in 19 TAC §241.15 needed to be modernized and aligned with the commissioner's principal appraisal standards found in 19 TAC Chapter 149.

At its March 2015 meeting, the SBEC approved the standards review committee for 19 TAC Chapter 241. The committee met in April 2015 to develop recommended changes to the principal standards. The committee subsequently worked with TEA staff to provide additional feedback prior to presenting draft rule changes to the SBEC at the December 2016 meeting.

The proposed rule actions would repeal the current principal standards and replace them with new principal standards. Proposed new 19 TAC §241.15 would better align the standards with the knowledge and skills required for today's principals and with the commissioner's principal appraisal standards. The proposed new section would also elevate school culture and instructional leadership as two areas of principal development that should receive additional and focused attention by preparation programs. The proposed rule actions also result from the SBEC's rule review of 19 TAC Chapter 241 conducted in accordance with Texas Government Code, §2001.039.

The proposed rule actions would have no procedural and reporting implications. Also, the proposed rule actions would have no locally maintained paperwork requirements.

FISCAL NOTE. Ryan Franklin, associate commissioner for educator leadership and quality, has determined that for the first five-year period the proposed repeal and new section are in effect there will be fiscal implications based on costs for state government (TEA) as a result of enforcing or administering the proposed repeal and new section for fiscal year (FY) 2017. Revising the principal standards for certification would lead to the creation of a new principal certification examination that would align with the new standards. The creation of the new examination is estimated to cost approximately \$265,000. There are no additional costs to local government as a result of enforcing or administering the proposed repeal and new section.

PUBLIC BENEFIT/COST NOTE. Mr. Franklin has determined that for the first five-year period the proposed repeal and new section are in effect the public and student benefit anticipated as a result of the proposed repeal and new section would be the alignment of principal preparation and certification standards with contemporary principal practices and principal appraisal and professional development standards, which will lead to better development of principals throughout their careers. There are no additional costs to persons required to comply with the proposed repeal and new section.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND MICROBUSINESSES. There is no direct adverse economic impact for small businesses and microbusinesses; therefore, no regulatory flexibility analysis, specified in Texas Government Code, §2006.002, is required.

REQUEST FOR PUBLIC COMMENT. The public comment period on the proposal begins March 11, 2016, and ends April 11, 2016. The SBEC will take registered oral and written comments on proposed repeal and new 19 TAC §241.15 at the April 15, 2016 meeting in accordance with the SBEC board operating policies and procedures. Comments on the proposal may be submitted to Cristina De La Fuente-Valadez, Rulemaking, Texas Education Agency, 1701 North Congress Avenue, Austin, Texas 78701, (512) 475-1497. Comments may also be submitted electronically to sbecrules@tea.texas.gov or faxed to (512) 463-5337. All requests for a public hearing on the proposed repeal and new section submitted under the Administrative Procedure Act must be received by the Department of Educator Leadership and Quality, Texas Education Agency, 1701 North Congress Avenue, Austin, Texas 78701, Attention: Mr. Ryan Franklin, associate commissioner for educator leadership and quality, not more than 14 calendar days after notice of the proposal has been published in the *Texas Register* on March 11, 2016.

19 TAC §241.15

STATUTORY AUTHORITY. The repeal is proposed under the Texas Education Code (TEC), §21.003(a), which states that a person may not be employed as a teacher, teacher intern or teacher trainee, librarian, educational aide, administrator, educational diagnostician, or school counselor by a school district unless the person holds an appropriate certificate or permit issued as provided by the TEC, Chapter 21, Subchapter B; §21.041(b)(4), which requires the State Board for Educator Certification (SBEC) to propose rules that specify the requirements for the issuance and renewal of an educator certificate; §21.046(b), which states that the qualifications for certification as a principal must be sufficiently flexible so that an outstanding teacher may qualify by substituting approved experience and professional training for part of the educational requirements; §21.046(c), which states that because an effective principal is essential to school improvement, the SBEC shall ensure that each candidate for certification as a principal is of the highest caliber and that multi-level screening processes, validated comprehensive assessment programs, and flexible internships with successful mentors exist to determine whether a candidate for certification as a principal possesses the essential knowledge, skills, and leadership capabilities necessary for success; and §21.046(d), which states that in creating the qualifications for certification as a principal, the SBEC shall consider the knowledge, skills, and proficiencies for principals as developed by relevant national organizations and the State Board of Education.

CROSS REFERENCE TO STATUTE. The proposed repeal implements the TEC, §§21.003(a), 21.041(b)(4), and 21.046(b)-(d).

§241.15. Standards Required for the Principal Certificate.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 29, 2016.

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Cristina De La Fuente-Valadez

Director, Rulemaking, Texas Education Agency

State Board for Educator Certification

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For further information, please call: (512) 475-1497



19 TAC §241.15

STATUTORY AUTHORITY. The new section is proposed under the Texas Education Code (TEC), §21.003(a), which states that a person may not be employed as a teacher, teacher intern or teacher trainee, librarian, educational aide, administrator, educational diagnostician, or school counselor by a school district unless the person holds an appropriate certificate or permit issued as provided by the TEC, Chapter 21, Subchapter B; §21.041(b)(4), which requires the State Board for Educator Certification (SBEC) to propose rules that specify the requirements for the issuance and renewal of an educator certificate; §21.046(b), which states that the qualifications for certification as a principal must be sufficiently flexible so that an outstanding teacher may qualify by substituting approved experience and professional training for part of the educational requirements; §21.046(c), which states that because an effective principal is essential to school improvement, the SBEC shall ensure that each candidate for certification as a principal is of the highest caliber and that multi-level screening processes, validated comprehensive assessment programs, and flexible internships with successful mentors exist to determine whether a candidate for certification as a principal possesses the essential knowledge, skills, and leadership capabilities necessary for success; and §21.046(d), which states that in creating the qualifications for certification as a principal, the SBEC shall consider the knowledge, skills, and proficiencies for principals as developed by relevant national organizations and the State Board of Education.

CROSS REFERENCE TO STATUTE. The proposed new section implements the TEC, §§21.003(a), 21.041(b)(4), and 21.046(b)-(d).

§241.15. Standards Required for the Principal Certificate.

(a) Principal Certificate Standards. The knowledge and skills identified in this section must be used by an educator preparation program in the development of curricula and coursework and by the State Board for Educator Certification as the basis for developing the examinations required to obtain the standard Principal Certificate. The standards also serve as the foundation for the individual assessment, professional growth plan, and continuing professional education activities required by §241.30 of this title (relating to Requirements to Renew the Standard Principal Certificate).

(b) School Culture. The principal:

(1) ensures that a positive, collaborative, and collegial school culture facilitates and enhances the implementation of campus initiatives and the achievement of campus goals;

(2) uses emerging issues, recent research, demographic data, knowledge of systems, campus climate inventories, student learning data, and other information to collaboratively develop a shared campus vision;

(3) facilitates the collaborative development of a plan in which objectives and strategies to implement the campus vision are clearly articulated;

(4) supports the implementation of the campus vision by aligning financial, human, and material resources;

(5) establishes processes to assess and modify the plan of implementation to ensure achievement of the campus vision;

(6) acknowledges, recognizes, and celebrates the contributions of students, staff, parents, and community members toward the realization of the campus vision;

(7) models and promotes the continuous and appropriate development of all learners, including faculty and staff, in the campus community;

(8) uses strategies to ensure the development of collegial relationships and effective collaboration of campus staff;

(9) develops and uses effective conflict-management and consensus-building skills;

(10) establishes and communicates consistent expectations for staff and students, providing supportive feedback to ensure a positive campus environment;

(11) implements effective strategies to systematically gather input from all campus stakeholders, supporting innovative thinking and an inclusive culture;

(12) creates an atmosphere of safety that encourages the social, emotional, and physical well-being of staff and students; and

(13) ensures that parents and other members of the community are an integral part of the campus culture.

(c) Leading Learning. The principal:

(1) creates a campus culture that sets high expectations, promotes learning, and provides intellectual stimulation for self, students, and staff;

(2) prioritizes instruction and student achievement by understanding, sharing, and promoting a clear definition of high-quality instruction based on best practices from recent research;

(3) routinely monitors and improves instruction by visiting classrooms, engaging in formative, evidence-based appraisal processes and conferences with teachers, and attending grade or team meetings;

(4) facilitates the use of sound research-based practice in the development and implementation of campus curricular, co-curricular, and extracurricular programs to fulfill academic, developmental, social, and cultural needs;

(5) facilitates campus participation in collaborative school district planning, implementation, monitoring, and curriculum revision to ensure appropriate scope, sequence, content, and alignment;

(6) implements a rigorous curriculum aligned with state standards, including college and career readiness standards;

(7) analyzes the curriculum to ensure that teachers align content across grades and that curricular scopes and sequences meet the particular needs of their diverse student populations;

(8) monitors and ensures staff uses multiple forms of student data to inform instruction and intervention decisions to maximize instructional effectiveness and student achievement;

(9) ensures that effective instruction maximizes growth of individual students and student groups, supports equity, and eliminates the achievement gap;

(10) ensures staff have the capacity and time to collaboratively and individually use classroom formative and summative assessment data to inform effective instructional practices and interventions; and

(11) facilitates the use and integration of technology, telecommunications, and information systems that enhance learning.

(d) Human Capital. The principal:

(1) invests and manages time to prioritize the development, support, and supervision of the staff to enhance student outcomes;

(2) ensures all staff have clear expectations that guide them and by which they are assessed, including the use of and familiarity with evidence-based appraisal rubrics, where applicable;

(3) uses data from multiple points of the year to complete accurate appraisals of all staff, using evidence from regular observations, student data, and other sources to evaluate the effectiveness of teachers and staff;

(4) coaches and develops educators by conducting conferences, giving individualized feedback, and supporting individualized professional growth opportunities;

(5) facilitates the campus's professional learning community to review data, processes, and policies in order to improve teaching and learning in the school;

(6) creates opportunities for effective staff to take on a variety of leadership roles and appropriately delegates responsibilities to staff and administrators on the leadership team;

(7) collaboratively develops, implements, and revises a comprehensive and on-going plan for professional development of campus staff that addresses staff needs based on staff appraisal trends, goals, and student information;

(8) ensures the effective implementation of a continuum of professional development by the appropriate allocation of time, funding, and other needed resources;

(9) implements effective, legal, and appropriate strategies for the recruitment, selection, assignment, and induction of campus staff; and

(10) plans for and adopts early hiring practices.

(e) Executive Leadership. The principal:

(1) reflects on his or her practice, seeks and acts on feedback, and strives to continually improve, learn, and grow;

(2) engages in ongoing and meaningful professional growth activities to further develop knowledge and skills and to model lifelong learning;

(3) uses strong communication skills, understands how to communicate a message in different ways to meet the needs of various audiences, and develops and implements strategies for effective internal and external communications;

(4) develops and implements a comprehensive program of community relations, which uses strategies that will effectively involve and inform multiple constituencies;

(5) establishes partnerships with parents, businesses, and other groups in the community to strengthen programs and support campus goals;

(6) demonstrates awareness of social and economic issues that exist within the school and community that could impact campus operations and student learning;

(7) gathers and organizes information from a variety of sources for use in creative and effective campus decision making;

(8) frames, analyzes, and creatively resolves campus problems using effective problem-solving techniques to make timely, high-quality decisions;

(9) develops, implements, and evaluates change processes for organizational effectiveness;

(10) uses effective planning, time management, and organization of work to maximize attainment of school district and campus goals; and

(11) keeps staff inspired and focused on the campus vision while supporting effective change management.

(f) Strategic Operations. The principal:

(1) assesses current campus needs, reviewing a wide set of evidence to determine the campus's priorities, and sets ambitious and measurable school goals, targets, and strategies that form the campus's strategic plan;

(2) outlines and tracks meaningful goals, targets, and strategies aligned to a school vision that continuously improves teacher effectiveness and student outcomes;

(3) allocates resources effectively (e.g., staff time, dollars, and tools), aligning them to the school priorities and goals, and works to access additional resources as needed to support learning;

(4) establishes structures to regularly monitor multiple data points with leadership teams to evaluate progress toward goals, adjusting strategies to improve effectiveness;

(5) implements appropriate management techniques and group processes to define roles, assign functions, delegate authority, and determine accountability for campus goal attainment;

(6) implements strategies that enable the physical plant, equipment, and support systems to operate safely, efficiently, and effectively to maintain a conducive learning environment;

(7) applies local, state, and federal laws and policies to support sound decisions while considering implications related to all school operations and programs;

(8) collaboratively plans and effectively manages the campus budget;

(9) uses technology to enhance school management;

(10) facilitates the effective coordination of campus curricular, co-curricular, and extracurricular programs in relation to each other and other school district programs; and

(11) collaborates with district staff to implement district policies and advocates for the needs of district students and staff.

(g) Ethics, Equity, and Diversity. The principal:

(1) implements policies and procedures that encourage all campus personnel to comply with Chapter 247 of this title (relating to Educators' Code of Ethics);

(2) models and promotes the highest standard of conduct, ethical principles, and integrity in decision making, actions, and behaviors;

(3) ensures that reports of educator misconduct, including inappropriate relationships between educators and students, are properly reported so appropriate investigations can be conducted;

(4) models and promotes the continuous and appropriate development of all learners in the campus community;

(5) ensures all students have access to effective educators and continuous learning opportunities;

(6) promotes awareness and appreciation of diversity throughout the campus community;

(7) implements special campus programs to ensure that all students are provided quality, flexible instructional programs and services to meet individual student needs;

(8) articulates the importance of education in creating engaged citizens in a free democratic society;

(9) communicates productively with all audiences through strong communication skills and understands how to communicate a message in different ways to meet the needs of various audiences; and

(10) treats all members of the community with respect and develops strong, positive relationships with them.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 29, 2016.

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Cristina De La Fuente-Valadez

Director, Rulemaking, Texas Education Agency

State Board for Educator Certification

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For further information, please call: (512) 475-1497



TITLE 22. EXAMINING BOARDS

PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 283. LICENSING REQUIREMENTS FOR PHARMACISTS

22 TAC §§283.4, 283.7, 283.8, 283.11

The Texas State Board of Pharmacy proposes amendments to §283.4, concerning Internship Requirements, §283.7, concerning Examination Requirements, §283.8, concerning Reciprocity Requirements, and §283.11, concerning Examination Retake Requirements. The amendments to §§283.4, 283.7, and 283.8, if adopted, eliminate the provisions allowing individuals who are unable to obtain a social security number to provide an individual taxpayer identification number in lieu of a social security number because a social security number is required in order to process criminal background checks. The amendments to §283.11, if adopted, implement provisions of S.B. 460 passed during the 84th Texas Legislative session allowing applicants apply for a Texas pharmacist license who fail to achieve the minimum passing grade to retake the NAPLEX and MPJE examinations four additional times for a total of five times.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rules.

Ms. Dodson has determined that, for each year of the first five-year period the rules will be in effect, the public benefit anticipated as a result of enforcing the amendments will ensure individuals applying for a pharmacist license meet the requirements in order to conduct criminal background checks and are allowed the appropriate number of times to retake licensing examinations. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with these sections.

Written comments on the amendments may be submitted to Allison Vordenbaumen 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) 305-6778. Comments must be received by 5 p.m., April 25, 2016.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 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 these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§283.4. Internship Requirements.

(a) Goals and competency objectives of internship.

(1) The goal of internship is for the pharmacist-intern to attain the knowledge, skills, and abilities to safely, efficiently, and effectively provide pharmacist-delivered patient care to a diverse patient population and practice pharmacy under the laws and regulations of the State of Texas.

(2) The following competency objectives are necessary to accomplish the goal of internship in paragraph (1) of this subsection.

(A) Provides drug products. The pharmacist-intern shall demonstrate competence in determining the appropriateness of prescription drug orders and medication orders; evaluating and selecting products; and assuring the accuracy of the product/prescription dispensing process.

(B) Communicates with patients and/or patients' agents about prescription drugs. The pharmacist-intern shall demonstrate competence in interviewing and counseling patients, and/or the patients' agents, on drug usage, dosage, packaging, routes of administration, intended drug use, and storage; discussing drug cautions, adverse effects, and patient conditions; explaining policies on fees and services; relating to patients in a professional manner; and interacting to confirm patient understanding.

(C) Communicates with patients and/or patients' agents about nonprescription products, devices, dietary supplements, diet, nutrition, traditional nondrug therapies, complementary and alternative therapies, and diagnostic aids. The pharmacist-intern shall demonstrate competence in interviewing and counseling patients and/or patients' agents on conditions, intended drug use, and adverse effects; assisting in and recommending drug selection; triaging and assessing the need for treatment or referral, including referral for a patient seeking pharmacist-guided self-care; providing information on medical/surgi-

cal devices and home diagnostic products; and providing poison control treatment information and referral.

(D) Communicates with healthcare professionals and patients and/or patients' agents. The pharmacist-intern shall demonstrate competence in obtaining and providing accurate and concise information in a professional manner and using appropriate oral, written, and nonverbal language.

(E) Practices as a member of the patient's interdisciplinary healthcare team. The pharmacist-intern shall demonstrate competence in collaborating with physicians, other healthcare professionals, patients, and/or patients' agents to formulate a therapeutic plan. The pharmacist-intern shall demonstrate competence in establishing and interpreting data-bases, identifying drug-related problems and recommending appropriate pharmacotherapy specific to patient needs, monitoring and evaluating patient outcomes, and devising follow-up plans.

(F) Maintains professional-ethical standards. The pharmacist-intern is required to comply with laws and regulations pertaining to pharmacy practice; to apply professional judgment; to exhibit reliability and credibility in dealing with others; to deal professionally and ethically with colleagues and patients; to demonstrate sensitivity and empathy for patients/care givers; and to maintain confidentiality.

(G) Compounds. The pharmacist-intern shall demonstrate competence in using acceptable professional procedures; selecting appropriate equipment and containers; appropriately preparing compounded non-sterile and sterile preparations; and documenting calculations and procedures. Pharmacist-interns engaged in compounding non-sterile preparations shall meet the training requirements for pharmacists specified in §291.131 of this title (relating to Pharmacies Compounding Non-sterile Preparations). Pharmacist-interns engaged in compounding sterile preparations shall meet the training requirements for pharmacists specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(H) Retrieves and evaluates drug information. The pharmacist-intern shall demonstrate competence in retrieving, evaluating, managing, and using the best available clinical and scientific publications for answering a drug-related request in a timely fashion and assessing, evaluating, and applying evidence based information to promote optimal health care. The pharmacist-intern shall perform investigations on relevant topics in order to promote inquiry and problem-solving with dissemination of findings to the healthcare community and/or the public.

(I) Manages general pharmacy operations. The pharmacist-intern shall develop a general understanding of planning, personnel and fiscal management, leadership skills, and policy development. The pharmacist-intern shall have an understanding of drug security, storage and control procedures and the regulatory requirements associated with these procedures, and maintaining quality assurance and performance improvement. The pharmacist-intern shall observe and document discrepancies and irregularities, keep accurate records and document actions. The pharmacist-intern shall attend meetings requiring pharmacy representation.

(J) Participates in public health, community service or professional activities. The pharmacist-intern shall develop basic knowledge and skills needed to become an effective healthcare educator and a responsible participant in civic and professional organizations.

(K) Demonstrates scientific inquiry. The pharmacist-intern shall develop skills to expand and/or refine knowledge in the areas of pharmaceutical and medical sciences or pharmaceutical services. This may include data analysis of scientific, clinical, sociologi-

cal, and/or economic impacts of pharmaceuticals (including investigational drugs), pharmaceutical care, and patient behaviors, with dissemination of findings to the scientific community and/or the public.

(b) Hours requirement.

(1) The board requires 1,500 hours of internship for licensure. These hours may be obtained through one or more of the following methods:

(A) in a board approved student internship program, as specified in subsection (c) of this section;

(B) in a board-approved extended-internship program as specified in subsection (d) of this section; and/or

(C) graduation from a college/school of pharmacy after July 1, 2007. Persons graduating from such programs shall be credited 1,500 hours or the number of hours actually obtained and reported by the college; and/or

(D) internship hours approved and certified to the board by another state board of pharmacy.

(2) Pharmacist-interns participating in an internship may be credited no more than 50 hours per week of internship experience.

(3) Internship hours may be used for the purpose of licensure for no longer than two years from the date the internship is completed.

(c) College-/School-Based Internship Programs.

(1) Internship experience acquired by student-interns.

(A) An individual may be designated a student-intern provided he/she:

(i) submits an application to the board that includes the following information:

(I) name;

(II) addresses, phone numbers, date of birth, and social security number; [however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number;]

(III) college of pharmacy and expected graduation date; and

(IV) any other information requested on the application.

(ii) is enrolled in the professional sequence of a college/school of pharmacy;

(iii) has successfully completed the first professional year and obtained a minimum of 30 credit hours of work towards a professional degree in pharmacy; and

(iv) has met all requirements necessary for the board to access the criminal history records information, including submitting fingerprint information and being responsible for all associated costs.

(B) The terms of the student internship shall be as follows.

(i) The student internship shall be gained concurrent with college attendance, which may include:

(I) partial semester breaks such as spring breaks;

(II) between semester breaks; and

(III) whole semester breaks provided the student-intern attended the college/school in the immediate preceding semester and is scheduled with the college/school to attend in the immediate subsequent semester.

(ii) The student internship shall be obtained in pharmacies licensed by the board, federal government pharmacies, or in a board-approved program.

(iii) The student internship shall be in the presence of and under the supervision of a healthcare professional preceptor or a pharmacist preceptor.

(C) None of the internship hours acquired outside of a school-based program may be substituted for any of the hours required in a college/school of pharmacy internship program.

(2) Expiration date for student-intern designation.

(A) The student-internship expires:

(i) if the student-intern voluntarily or involuntarily ceases enrollment, including suspension, in a college/school of pharmacy;

(ii) the student-intern fails either the NAPLEX or Texas Pharmacy Jurisprudence Examinations specified in this section; or

(iii) the student-intern fails to take either the NAPLEX or Texas Pharmacy Jurisprudence Examinations or both within six calendar months after graduation.

(B) The executive director of the board, in his/her discretion may extend the term of the student internship if administration of the NAPLEX or Texas Pharmacy Jurisprudence Examinations is suspended or delayed.

(3) Texas colleges/schools of pharmacy internship programs.

(A) Intern-trainees and student-interns completing a board-approved Texas college/school-based structured internship shall be credited the number of hours actually obtained and reported by the college. No credit shall be awarded for didactic experience.

(B) No more than 600 hours of the required 1,500 hours may be obtained under a healthcare professional preceptor except when a pharmacist-intern is working in a federal government pharmacy.

(C) Individuals enrolled in the professional sequence of a Texas college/school of pharmacy may be designated as a intern-trainee provided he/she:

(i) submits an application to the board that includes the following information:

(I) name;

(II) addresses, phone numbers, date of birth, and social security number; [however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number;]

(III) college of pharmacy and expected graduation date; and

(IV) any other information requested on the application.

(ii) is enrolled in the professional sequence of a college/school of pharmacy; and

(iii) has met all requirements necessary for the board to access the criminal history records information, including submitting fingerprint information and being responsible for all associated costs. Such internship shall remain in effect during the time the intern-trainee is enrolled in the first year of the professional sequence and shall expire upon completion of the first year of the professional sequence or upon separation from the professional sequence.

(d) Extended-internship program.

(1) A person may be designated an extended-intern provided he/she has met one of the following requirements:

(A) passed NAPLEX and the Texas Pharmacy Jurisprudence Examinations but lacks the required number of internship hours for licensure;

(B) applied to the board to take the NAPLEX and Texas Jurisprudence Examinations within six calendar months after graduation and has:

(i) graduated and received a professional degree from a college/school of pharmacy; or

(ii) completed all of the requirements for graduation and receipt of a professional degree from a college/school of pharmacy;

(C) applied to the board to take the NAPLEX and Texas Jurisprudence Examinations within six calendar months after obtaining full certification from the Foreign Pharmacy Graduate Equivalency Commission;

(D) applied to the board for re-issuance of a pharmacist license which has expired for more than two years but less than ten years and has successfully passed the Texas Pharmacy Jurisprudence Examination, but lacks the required number of hours of internship or continuing education required for licensure;

(E) is a resident in a residency program accredited by the American Society of Health-System Pharmacists in the state of Texas; or

(F) been ordered by the Board to complete an internship.

(2) In addition to meeting one of the requirements in paragraph (1) of this subsection, an applicant for an extended-internship must:

(A) submit an application to the board that includes the following information:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; [however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number;]

(iii) any other information requested on the application; and

(B) meet all requirements necessary for the board to access the criminal history records information, including submitting fingerprint information and being responsible for all associated costs.

(3) The terms of the extended-internship shall be as follows.

(A) The extended-internship shall be board-approved and gained in a pharmacy licensed by the board, or a federal government pharmacy participating in a board-approved internship program.

(B) The extended-internship shall be in the presence of and under the direct supervision of a pharmacist preceptor.

(4) The extended internship remains in effect for two years. However, the internship expires immediately upon:

(A) the failure of the extended-intern to take the NAPLEX and Texas Pharmacy Jurisprudence Examinations within six calendar months after graduation or FPGEC certification;

(B) the failure of the extended-intern to pass the NAPLEX and Texas Pharmacy Jurisprudence Examinations specified in this section;

(C) upon termination of the residency program; or

(D) obtaining a Texas pharmacist license.

(5) The executive director of the board, in his/her discretion may extend the term of the extended internship if administration of the NAPLEX and/or Texas Pharmacy Jurisprudence Examinations is suspended or delayed.

(6) An applicant for licensure who has completed less than 500 hours of internship at the time of application shall complete the remainder of the 1,500 hours of internship and have the preceptor certify that the applicant has met the objectives listed in subsection (a) of this section.

(e) Pharmacist-intern identification.

(1) The board shall provide the pharmacist-intern written documentation of designation as a pharmacist-intern. This written documentation serves as identification and authorization to perform the duties of a pharmacist-intern as described in §283.5 of this title (relating to Pharmacist-Intern Duties).

(2) Pharmacist-interns shall keep this written documentation with them at all times they are serving as a pharmacist-intern and make it available for inspection by board agents.

(3) All pharmacist-interns shall wear an identification tag or badge which bears the person's name and identifies him or her as a pharmacist-intern.

(f) Change of address and/or name.

(1) Change of address. A pharmacist-intern shall notify the board electronically or in writing within 10 days of a change of address, giving the old and new address.

(2) Change of name. A pharmacist-intern shall notify the board in writing within 10 days of a change of name by:

(A) sending a copy of the official document reflecting the name change (e.g., marriage certificate, divorce decree, etc.);

(B) returning the current pharmacist-intern certificate which reflects the previous name; and

(C) paying a fee of \$20.

(g) Duplicate or amended certificate. The fee for issuance of a duplicate or amended pharmacist-intern registration certificate shall be \$20.

§283.7. Examination Requirements.

Each applicant for licensure by examination shall pass the Texas Pharmacy Jurisprudence Examination and the NAPLEX. The examination requirements shall be as follows:

(1) Prior to taking the required examination, the applicant shall:

(A) meet the educational and age requirements as set forth in §283.3 of this title (relating to Educational and Age Requirements);

(B) meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs; and

(C) submit an application to the board that includes the following information:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; [~~however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number;~~] and

(iii) any other information requested on the application.

(2) All applicants shall pass NAPLEX, which includes, at a minimum, the following subject areas:

(A) chemistry;

(B) mathematics;

(C) pharmacy;

(D) pharmacology; and

(E) practice of pharmacy.

(3) Effective October 1, 1979, the following requirements apply.

(A) To pass NAPLEX, an applicant shall make the following grades:

(i) a minimum grade of 60 on chemistry, mathematics, pharmacy, and pharmacology test;

(ii) a minimum grade of 75 on the practice of pharmacy test; and

(iii) a minimum average grade of 75 on the NAPLEX.

(B) Should the applicant fail to achieve a minimum grade of 60 in any of the tests set out in paragraph (2)(A) - (E) of this section or fail to achieve a minimum grade of 75 in the practice of pharmacy test or fail to achieve a minimum average grade of 75 in the NAPLEX, such applicant, in order to be licensed, is required to retake all tests until such time as the minimum average grades are achieved.

(4) Effective June 1, 1986, the following requirements apply.

(A) To pass the NAPLEX, an applicant shall make a minimum average grade of 75.

(B) Should the applicant fail to achieve a minimum average grade of 75 in the NAPLEX, such applicant, in order to be licensed, shall retake the NAPLEX, as specified in §283.11 of this title (relating to Examination Retake Requirements) until such time as a minimum average grade of 75 is achieved.

(5) To pass the Texas Pharmacy Jurisprudence Examination, an applicant shall make a minimum grade of 75. Should the applicant fail to achieve a minimum grade of 75 on the Texas Pharmacy Jurisprudence Examination, such applicant, in order to be licensed, shall retake the Texas Pharmacy Jurisprudence Examination as specified in §283.11 of this title until such time as a minimum average grade of 75 is achieved.

(6) A passing grade on an examination may be used for the purpose of licensure for a period of two years from the date of passing the examination.

(7) Each applicant for licensure by examination utilizing NAPLEX scores transferred from another state shall meet the following requirements for licensure in addition to the requirements set out in paragraphs (1) - (6) of this section.

(A) The applicant shall request NABP to transfer NAPLEX scores to the board. Such request shall be in accordance with NABP policy.

(B) The applicant shall pay the fee set out in §283.9 of this title.

(8) The NAPLEX and Texas Pharmacy Jurisprudence Examination shall be administered in compliance with the Americans with Disabilities Act of 1990 (42 U.S.C. Section 12101 et seq.) and in accordance with NABP policy.

(9) The board, in accordance with NABP policy, shall provide reasonable accommodations for an applicant diagnosed as having dyslexia, as defined in §51.970, Texas Education Code. The applicant shall provide:

(A) written documentation from a licensed physician which indicates that the applicant has been diagnosed as having dyslexia; and

(B) a written request outlining the reasonable accommodations requested.

§283.8. Reciprocity Requirements.

(a) All applicants for licensure by reciprocity shall:

(1) meet the educational and age requirements specified in §283.3 of this title (relating to Educational and Age Requirements);

(2) meet all requirements necessary in order for the board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs;

(3) complete the Texas and NABP applications for reciprocity. Any fraudulent statement made in the application for reciprocity is grounds for denial of the application; if such application is granted, any fraudulent statement is grounds for suspension, revocation, and/or cancellation of any license so granted by the board. The Texas application includes the following information:

(A) name;

(B) addresses, phone numbers, dates of birth, and social security numbers; [~~however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number;~~] and

(C) any other information requested on the application.

(4) shall present to the board proof of initial licensing by examination and proof that their current license and any other license or licenses granted to the applicant by any other state have not been

suspended, revoked, canceled, surrendered, or otherwise restricted for any reason; and

(5) shall pass the Texas Pharmacy Jurisprudence Examination with a minimum grade of 75. (The passing grade may be used for the purpose of licensure by reciprocity for a period of two years from the date of passing the examination.) Should the applicant fail to achieve a minimum grade of 75 on the Texas Pharmacy Jurisprudence Examination, such applicant, in order to be licensed, shall retake the Texas Pharmacy Jurisprudence Examination as specified in §283.11 of this title (relating to Examination Retake Requirements) until such time as a minimum grade of 75 is achieved.

(b) A reciprocity applicant originally licensed after January 1, 1978, and who has graduated and received a professional degree from a college of pharmacy, shall show proof such applicant has passed the NAPLEX or equivalent examination based on criteria no less stringent than the criteria in force in Texas.

(c) A reciprocity applicant who is a foreign pharmacy graduate shall provide written documentation that such applicant has:

(1) obtained full certification from the FPGEC; and

(2) passed NAPLEX or equivalent examination based on criteria no less stringent than the criteria in force in Texas.

(d) An applicant is not eligible for licensing by reciprocity unless the state in which the applicant is currently or was initially licensed as a pharmacist also grants reciprocal licensing to pharmacists duly licensed by examination in this state, under like circumstances and conditions.

§283.11. Examination Retake Requirements.

(a) Licensing by examination. Should an applicant fail to achieve the minimum grade on the NAPLEX or Texas Pharmacy Jurisprudence Examination or both, the following is applicable.

(1) If the applicant fails to achieve the minimum grade on NAPLEX as specified in §283.7 of this title (relating to Examination Requirements), the applicant may retake NAPLEX ~~four~~ four additional times for a total of ~~five~~ five exam administrations. Prior to any subsequent retakes of NAPLEX, the applicant must:

(A) request in writing an analysis of the applicant's performance on the most recent NAPLEX and provide this analysis to the Examination Retake Committee;

(B) complete college course work in subject areas recommended by the Examination Retake Committee;

(C) submit documentation from the Examination Retake Committee which specifies that the applicant has successfully completed the course work specified; and

(D) comply with the requirements of §283.7 of this title (relating to Examination Requirements).

(2) If the applicant fails to achieve the minimum grade on the Texas Pharmacy Jurisprudence Examination as specified in §283.7 of this title (relating to Examination Requirements), the applicant may retake the examination ~~four~~ four additional times for a total of ~~five~~ five exam administrations. Prior to any subsequent retake of the Texas Pharmacy Jurisprudence Examination, the applicant must:

(A) request in writing an analysis of the applicant's performance on the most recent Texas Pharmacy Jurisprudence Examination and provide this analysis to the Examination Retake Committee;

(B) complete college course work recommended by the Examination Retake Committee;

(C) submit documentation from the Examination Retake Committee which specifies that the applicant has successfully completed the recommended college course work; and

(D) comply with the requirements of §283.7 of this title (relating to Examination Requirements).

(3) If the applicant fails to achieve the minimum grade on both NAPLEX and the Texas Pharmacy Jurisprudence Examination, the applicant shall retake the examinations until a passing grade is achieved on one of the examinations. Such retakes shall be as specified in paragraphs (1) and (2) of this subsection.

(b) Licensing by reciprocity. If an applicant fails to achieve the minimum grade on the Texas Pharmacy Jurisprudence Examination as specified in §283.8 of this title (relating to Reciprocity Requirements), the applicant may retake the examination ~~four~~ four additional times for a total of ~~five~~ five exam administrations. Prior to any subsequent retake of the Texas Pharmacy Jurisprudence Examination, the applicant must:

(1) request in writing an analysis of the applicant's performance on the most recent Texas Pharmacy Jurisprudence Examination and provide this analysis to the Examination Retake Committee;

(2) complete college course work recommended by the Examination Retake Committee;

(3) submit documentation from the Examination Retake Committee which specifies that the applicant has successfully completed the recommended college course work; and

(4) comply with the requirements of §283.8 of this title (relating to Reciprocity Requirements).

(c) Examination Retake Committee. The board shall appoint one representative from each Texas college/school of pharmacy and one current board member to serve on the Examination Retake Committee. The Examination Retake Committee shall:

(1) meet as necessary but no more than twice each calendar year;

(2) review the analysis of an applicant's performance on failed examination(s);

(3) recommend college course work which the applicant must successfully complete before the applicant may retake the examination(s);

(4) specify the requirements for completion of the recommended college course work and the documentation required to validate successful completion of the recommended college course work; and

(5) once the applicant has met the requirements set out by the committee, certify to the board that the applicant has successfully completed the required college course work.

(d) College course work. For the purpose of this subsection, college course work shall be:

(1) one or more standard courses or self-paced work offered in a college of pharmacy's academic program; or

(2) one or more courses presented by a board-approved provider of continuing pharmacy education as specified in §295.8 of this title (relating to Continuing Education Requirements); or

(3) any course specified by the Examination Retake Committee.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 26, 2016.

TRD-201600946

Gay Dodson, R. Ph.

Executive Director

Texas State Board of Pharmacy

Earliest possible date of adoption: April 10, 2016

For further information, please call: (512) 305-8026



CHAPTER 291. PHARMACIES

SUBCHAPTER A. ALL CLASSES OF PHARMACIES

22 TAC §291.5, §291.14

The Texas State Board of Pharmacy proposes amendments to §291.5, concerning Closing a Pharmacy, and §291.14, concerning Pharmacy License Renewal. The amendments to §291.5 if adopted, clarify the requirements for closing a pharmacy and eliminate the requirements for a pharmacy to transfer records to a pharmacy within a reasonable distance. The amendments to §291.14, if adopted, implement provisions of S.B. 460 passed during the 84th Texas Legislative session which change the expiration date for a pharmacy license that has expired from one year to 91 days and allows the board to not renew the license of a pharmacy if the board determines that the pharmacy is not located or no longer exists at the pharmacy's address of record.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rules.

Ms. Dodson has determined that, for each year of the first five-year period the rules will be in effect, the public benefit anticipated as a result of enforcing the amendments to §291.5 will ensure that pharmacies that close provide adequate notice and the public benefit anticipated as a result of enforcing the amendments to §291.14 will ensure that pharmacies no longer operating are not renewed and are closed in a reasonable time. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with these sections.

Written comments on the amendments may be submitted to Allison Vordenbaumen 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) 305-6778. Comments must be received by 5 p.m., April 25, 2016.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 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 these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.5. Closing a Pharmacy.

(a) Prior to closing. At least 14 days prior to the closing of a pharmacy that dispenses prescription drug orders, the pharmacist-in-charge shall post a closing notice sign in a conspicuous place in the front of the prescription department and at all public entrance doors to the pharmacy. Such closing notice sign shall contain the following information: [eomply with the following:]

(1) the date of closing; and [if the pharmacy is registered to possess controlled substances, send a written notification to the appropriate divisional office of the Drug Enforcement Administration (DEA) containing the following information:]

{(A) the name, address, and DEA registration number of the pharmacy;}

{(B) the anticipated date of closing;}

{(C) the name, address, and DEA registration number of the pharmacy acquiring the controlled substances; and}

{(D) the date on which the transfer of controlled substances will occur.}

(2) [If the pharmacy dispenses prescription drug orders, post a closing notice sign in a conspicuous place in the front of the prescription department and at all public entrance doors to the pharmacy. Such closing notice sign shall contain the following information:]

{(A) the date of closing; and}

{(B)} the name, address, and telephone number of the pharmacy acquiring the prescription drug orders, including refill information and patient medication records of the pharmacy.

(b) Closing day. On the date of closing, the pharmacist-in-charge shall comply with the following:

(1) take an inventory as specified in §291.17 of this title (relating to Inventory Requirements);

(2) remove all prescription drugs from the pharmacy by one or a combination of the following methods:

(A) return prescription drugs to manufacturer or supplier (for credit/disposal);

(B) transfer (sell or give away) prescription drugs to a person who is legally entitled to possess drugs, such as a hospital, or another pharmacy; and

(C) destroy the prescription drugs following procedures specified in §303.2 of this title (relating to Disposal of Stock Prescription Drugs);

(3) if the pharmacy dispenses prescription drug orders:

(A) transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy [within a reasonable distance of the closing pharmacy]; and

(B) remove [move] all signs or notify the landlord or owner of the property that it is unlawful to use the word "pharmacy" either in English or any other language, or any other word or combination of words of the same or similar meaning, or any graphic representation that would mislead or tend to mislead the public that a pharmacy is located at the address.

(c) After closing.

(1) Within ten days after the closing of the pharmacy, the pharmacist-in-charge shall forward to the board a written notice of the closing which includes the following information:

- (A) the actual date of closing;
- (B) the license issued to the pharmacy;
- (C) a statement attesting:

(i) that an inventory as specified in §291.17 of this title (relating to Inventory Requirements) has been conducted; and

(ii) the manner by which the dangerous drugs and controlled substances possessed by the pharmacy were transferred or disposed; and

(D) if the pharmacy dispenses prescription drug orders, the name and address of the pharmacy to which the prescription drug orders, including refill information, and patient medication records were transferred.

(2) If the pharmacy is registered to possess controlled substances, send notification [a letter] to the[~~]~~

~~[(A)]~~ appropriate DEA divisional office explaining that the pharmacy has closed and include[- include] the following items ~~[with the letter]~~:

(A) ~~[(+)]~~ DEA registration certificate; and

(B) ~~[(+)]~~ all unused DEA order forms (222) with the word VOID written on the face of each order form[~~]; and~~

~~[(+)]~~ copy 2 of any DEA order forms (222) used to transfer Schedule II controlled from the closed pharmacy.

~~[(B)]~~ the Texas Department of Public Safety (DPS) explaining that the pharmacy has closed and include the DPS registration certificate.~~]~~

(3) Once the pharmacy has notified the board that the pharmacy is closed, the license may not be renewed. The pharmacy may apply for a new license as specified in §291.1 of this title (relating to Pharmacy License Application).

(d) Emergency closing. If pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances and the pharmacist-in-charge cannot provide notification 14 days prior to the closing, the pharmacist-in-charge shall comply with the provisions of subsection (a) of this section as far in advance of the closing as allowed by the circumstances.

(e) Joint responsibility. If the pharmacist-in-charge is not available to comply with the requirements of this section, the owner shall be responsible for compliance with the provisions of this section.

§291.14. *Pharmacy License Renewal.*

(a) Renewal requirements.

(1) A license to operate a pharmacy expires on the last day of the assigned expiration month.

~~[(2)]~~ Timely receipt of the completed application and renewal fee means the receipt in the board's office of such application and renewal fee.

(2) ~~[(3)]~~ The provision of the Act, §561.005, shall apply if the completed application and a renewal fee is not received in the board's office on or before the last day of the assigned expiration month.

(3) ~~[(4)]~~ An expired license may be renewed according to the following schedule:

(A) If the license has been expired for 90 days or less, the license may be renewed by paying to the board a renewal fee that

is equal to one and one-half times the required renewal fee as specified in §291.6 of this title (relating to Pharmacy License Fees).

~~[(B)]~~ If the license has been expired for more than 90 days but less than one year, the license may be renewed by paying to the board a renewal fee that is equal to two times the required renewal fee as specified in §291.6 of this title.~~]~~

(B) ~~[(C)]~~ If the license has been expired for 91 days [one year] or more, the license may not be renewed. The pharmacy may apply for a new license as specified in §291.1 of this title (relating to Pharmacy License Application).

(b) If the board determines on inspection at the pharmacy's address on or after the expiration date of the license that no pharmacy is located or exists at the pharmacy's address (e.g., the building is vacated or for sale or lease, or another business is operating at the location), the board shall not renew the license.

(c) ~~[(b)]~~ Additional renewal requirements for Class E pharmacies. In addition to the renewal requirements in subsection (a) of this section, a Class E pharmacy shall have on file with the Board an inspection report issued:

(1) not more than three years before the date the renewal application is received; and

(2) by the pharmacy licensing board in the state of the pharmacy's physical location except as provided in §291.104 of this title (relating to Operational Standards).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Gay Dodson, R.Ph.

Executive Director

Texas State Board of Pharmacy

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For further information, please call: (512) 305-8026



SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

22 TAC §291.34

The Texas State Board of Pharmacy proposes amendments to §291.34, concerning Records. The amendments, if adopted, clarify that prescriptions must be transferred within four business hours; clarify the requirements regarding identification records for individuals involved in dispensing; and implement provisions of HB 751 regarding interchangeable biological products.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments to §291.5 will ensure that pharmacies provide transfer information in a timely manner; ensure that records of individuals involved in dispensing

ing are accurate; and ensure prescription drug order information for interchangeable biological products is maintained. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with this section.

Written comments on the amendments may be submitted to Allison Vordenbaumen 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) 305-6778. Comments must be received by 5 p.m., April 25, 2016.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 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 these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.34. *Records.*

(a) (No change.)

(b) Prescriptions.

(1) - (6) (No change.)

(7) Prescription drug order information.

(A) (No change.)

(B) 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) 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 or biological product actually dispensed, if the drug was prescribed by generic name or interchangeable biological name or if a drug or interchangeable biological product other than the one prescribed was dispensed pursuant to the provisions of the Act, Chapters 562 and 563.

(8) - (10) (No change.)

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

(g) Transfer of prescription drug order information. For the purpose of initial or refill dispensing, the transfer of original prescription drug order information is permissible between pharmacies, subject to the following requirements.

(1) 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.

(2) 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.

(3) The transfer is communicated orally by telephone or via facsimile directly by a pharmacist to another pharmacist; by a pharmacist to a student-intern, extended-intern, or resident-intern; or by a student-intern, extended-intern, or resident-intern to another pharmacist.

(4) Both the original and the transferred prescription drug orders are maintained for a period of two years from the date of last refill.

(5) The individual transferring the prescription drug order information shall ensure the following occurs:

(A) write the word "void" on the face of the invalidated prescription or the prescription is voided in the data processing system;

(B) record the name, address, if for a controlled substance, the DEA registration number of the pharmacy to which it was transferred, and the name of the receiving individual on the reverse of the invalidated prescription or stored with the invalidated prescription drug order in the data processing system;

(C) record the date of the transfer and the name of the individual transferring the information; and

(D) if the prescription is transferred electronically, provide the following information:

(i) date of original dispensing and prescription number;

(ii) number of refills remaining and if a controlled substance, the date(s) and location(s) of previous refills;

(iii) name, address, and if a controlled substance, the DEA registration number of the transferring pharmacy;

(iv) name of the individual transferring the prescription; and

(v) if a controlled substance, name, address and DEA registration number, and prescription number from the pharmacy that originally dispensed the prescription, if different.

(6) The individual receiving the transferred prescription drug order information shall:

(A) write the word "transfer" on the face of the prescription or the prescription record indicates the prescription was a transfer; and

(B) reduce to writing all of the information required to be on a prescription as specified in subsection (b)(7) of this section (relating to Prescriptions) and including the following information;

(i) date of issuance and prescription number;

(ii) original number of refills authorized on the original prescription drug order;

(iii) date of original dispensing;

(iv) number of valid refills remaining and if a controlled substance, date(s) and location(s) of previous refills;

(v) name, address, and if for a controlled substance, the DEA registration number of the transferring pharmacy;

(vi) name of the individual transferring the prescription; and

(vii) name, address, and if for a controlled substance, the DEA registration number, of the pharmacy that originally dispensed the prescription, if different; or

(C) if the prescription is transferred electronically, create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription including all of the information required to be on a prescription as specified in subsection (b)(7) of this section (relating to Prescriptions) and the following:

(i) date of original dispensing;

(ii) number of refills remaining and if a controlled substance, the prescription number(s), date(s) and location(s) of previous refills;

(iii) name, address, and if for a controlled substance, the DEA registration number;

(iv) name of the individual transferring the prescription; and

(v) name, address, and if for a controlled substance, the DEA registration number, of the pharmacy that originally filled the prescription.

(7) Both the individual transferring the prescription and the individual receiving the prescription must engage in confirmation of the prescription information by such means as:

(A) the transferring individual faxes the hard copy prescription to the receiving individual; or

(B) the receiving individual repeats the verbal information from the transferring individual and the transferring individual verbally confirms that the repeated information is correct.

(8) Pharmacies transferring prescriptions electronically shall comply with the following:

(A) 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 or a pharmacist, and the prescription may be read to a pharmacist by telephone.

(B) 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.

(C) If the data processing system does not have the capacity to store all the information as specified in paragraphs (5) and (6) of this subsection, the pharmacist is required to record this information on the original or transferred prescription drug order.

(D) The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance prescription drug orders that have been previously transferred.

(E) Pharmacies electronically accessing the same prescription drug order records may electronically transfer prescription information if the following requirements are met.

(i) The original prescription is voided and the pharmacies' data processing systems shall store all the information as specified in paragraphs (5) and (6) of this subsection.

(ii) Pharmacies not owned by the same entity [~~person~~] may electronically access the same prescription drug order

records, provided the owner, chief executive officer, or designee of each pharmacy signs an agreement allowing access to such prescription drug order records.

(iii) An electronic transfer between pharmacies may be initiated by a pharmacist intern, pharmacy technician, or pharmacy technician trainee acting under the direct supervision of a pharmacist.

(9) An individual may not refuse to transfer original prescription information to another individual who is acting on behalf of a patient and who is making a request for this information as specified in this subsection. The transfer of original prescription information must be completed within four business hours of the request. [~~done in a timely manner.~~]

(10) When transferring a compounded prescription, a pharmacy is required to provide all of the information regarding the compounded preparation including the formula unless the formula is patented or otherwise protected, in which case, the transferring pharmacy shall, at a minimum, provide the quantity or strength of all of the active ingredients of the compounded preparation.

(11) [~~(10)~~] The electronic transfer of multiple or bulk prescription records between two pharmacies is permitted provided:

(A) a record of the transfer as specified in paragraph (5) of this subsection [~~section~~] is maintained by the transferring pharmacy;

(B) the information specified in paragraph (6) of this subsection is maintained by the receiving pharmacy; and

(C) in the event that the patient or patient's agent is unaware of the transfer of the prescription drug order record, the transferring pharmacy must notify the patient or patient's agent of the transfer and must provide the patient or patient's agent with the telephone number of the pharmacy receiving the multiple or bulk prescription drug order records.

(h) (No change.)

(i) Other records. Other records to be maintained by a pharmacy:

(1) a [~~permanent~~] log of the initials or identification codes that will identify each pharmacist, pharmacy technician, and pharmacy technician trainee, who is involved in the dispensing process, in the pharmacy's data processing system, [by name performing data entry of prescription information] (the initials or identification code shall be unique to ensure that each individual can be identified, i.e., identical initials or identification codes shall not be used). Such log shall be maintained at the pharmacy for at least seven years from the date of the transaction;

(2) Copy 3 of DEA order form (DEA 222) that has been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents and/or for each order filled using the DEA Controlled Substance Ordering System (CSOS) the original signed order and all linked records for that order;

(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);

(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 that 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

(j) - (l) (No change.)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Gay Dodson, R.Ph.

Executive Director

Texas State Board of Pharmacy

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For further information, please call: (512) 305-8026



SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES

22 TAC §291.133

The Texas State Board of Pharmacy proposes amendments to §291.133, concerning Pharmacies Compounding Sterile Preparations. The proposed amendments, if adopted, remove references to training requirements that are no longer necessary; update the requirements for sterility testing and temperature and humidity to be consistent with USP 797; clarify the requirements regarding blood labeling to specify that blood labeling occurs in a buffer area; and clarify recordkeeping requirements.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will ensure pharmacies are compounding sterile preparations under appropriate conditions. There might be an adverse economic effect on micro, small, and large businesses or to other entities/persons who are

required to comply with the rules for pharmacies compounding sterile preparations. Based on the significant variances in pharmacies' physical structure and layout, it is difficult for TSBP to determine the actual cost to businesses required to comply with this rule. These costs would involve bringing the sterile compounding area of pharmacies into compliance with the new provisions of the rules. In addition, TSBP is unable to reduce these costs because to do so would compromise the purposes of this rule which is intended to protect the health and safety of the public.

Written comments on the amendments may be submitted to Allison Vordenbaumen 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) 305-6778. Comments must be received by 5 p.m., April 25, 2016.

The amendments are proposed under §§551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 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 these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§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-S, Class B, Class C-S, and Class E-S pharmacies;

(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile preparation in Class A-S, Class B, Class C-S, and Class E-S pharmacies to a practitioner's office for office use by the practitioner;

(3) compounding and distribution of compounded sterile preparations by a Class A-S pharmacy for a Class C-S pharmacy; and

(4) compounding of sterile preparations by a Class C-S pharmacy and the distribution of the compounded preparations to other Class C or Class C-S 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) Ante-area--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--A mode of processing pharmaceutical and medical preparations that involves the separate sterilization of the preparation and of the package (containers-closures or packaging material for medical devices) and the transfer of the preparation into the container and its closure under at least ISO Class 5 conditions.

(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 or preparation, 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--An ISO Class 7 or, if a Class B pharmacy, ISO Class 8 or better, area where the primary engineering control area is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.

(12) Clean room--A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

(13) Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.

(14) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner's prescription drug or medication order based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or

(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §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) Compounding Aseptic Containment Isolator--A compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

(17) Compounding Personnel--A pharmacist, pharmacy technician, or pharmacy technician trainee who performs the actual compounding; a pharmacist who supervises pharmacy technicians or pharmacy technician trainees compounding sterile preparations, and a pharmacist who performs an intermediate or final verification of a compounded sterile preparation.

(18) Critical Area--An ISO Class 5 environment.

(19) Critical Sites--A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.

(20) 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.

(21) Direct Compounding Area--A critical area within the ISO Class 5 primary engineering control where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

(22) Disinfectant--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 and fungal spores. It refers to substances applied to inanimate objects.

(23) First Air--The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(24) Hazardous Drugs--Drugs that, studies in animals or humans indicate exposure to the drugs, have a potential for causing cancer, development or reproductive toxicity, or harm to organs. For the purposes of this chapter, radiopharmaceuticals are not considered hazardous drugs.

(25) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).

(26) HVAC--Heating, ventilation, and air conditioning.

(27) 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.

(28) IPA--Isopropyl alcohol (2-propanol).

(29) Labeling--All labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container.

(30) Media-Fill Test--A test 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 is substituted for the actual drug preparation 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.

(31) 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.

(32) 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.

(33) 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.

(34) 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).

(35) Repackaging--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.

(36) Preparation or Compounded Sterile Preparation--A sterile admixture compounded in a licensed pharmacy or other health-care-related facility pursuant to the order of a licensed prescriber. The components of the preparation may or may not be sterile products.

(37) 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, compounding aseptic isolators, and compounding aseptic containment isolators.

(38) Product--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.

(39) Positive Control--A quality assurance sample prepared to test positive for microbial growth.

(40) 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.

(41) 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.

(42) 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.

(43) Segregated Compounding Area--A designated space, either a demarcated area or room, that is restricted to preparing low-risk level compounded sterile preparations with 12-hour or less beyond-use date. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of compounded sterile preparations and shall be void of activities and materials that are extraneous to sterile compounding.

(44) Single-dose container--A single-unit container for articles or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include pre-filled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

(45) SOPs--Standard operating procedures.

(46) Sterilizing Grade Membranes--Membranes that are documented to retain 100% of a culture of 10⁷ microorganisms of a strain of *Brevundimonas* (*Pseudomonas*) *diminuta* per square

centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22-micrometer or 0.2-micrometer nominal pore size, depending on the manufacturer's practice.

(47) Sterilization by Filtration--Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

(48) 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 10⁻⁶ or a probability of less than one in one million of a non-sterile unit.

(49) Unidirectional Flow--An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

(50) 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.

(A) General.

(i) A pharmacist is responsible for ensuring that compounded sterile preparations are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.

(ii) A pharmacist shall inspect and approve all components, drug preparation containers, closures, labeling, and any other materials involved in the compounding process.

(iii) A pharmacist shall review all compounding records for accuracy and conduct periodic in-process checks as defined in the pharmacy's policy and procedures.

(iv) A pharmacist shall review all compounding records for accuracy and conduct a final check.

(v) A pharmacist is responsible for ensuring the proper maintenance, cleanliness, and use of all equipment used in the compounding process.

(vi) A pharmacist shall be accessible at all times, 24 hours a day, to respond to patients' and other health professionals' questions and needs.

~~[(B) Prior to September 1, 2015 - initial training and continuing education.]~~

~~[(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 paragraph (4)(D) of this subsection. 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. 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;]~~

~~[(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 this paragraph or paragraph (3) of this subsection.]~~

~~[(iii) All pharmacists engaged in compounding sterile preparations shall obtain continuing education appropriate for the type of compounding done by the pharmacist.]~~

~~[(B) [(C)] Initial [Effective September 1, 2015- initial] training and continuing education.~~

(i) All pharmacists who compound sterile preparations or supervise pharmacy technicians and pharmacy technician trainees compounding sterile preparations shall comply with the following:

(I) complete through a single course, a minimum of 20 hours of instruction and experience in the areas listed in paragraph

(4)(D) of this subsection. Such training shall be obtained through completion of a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE accredited provider;

(II) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides sufficient hours of instruction and experience in the facility's sterile compounding processes and procedures. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and

(III) 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 is actively engaged in performing sterile compounding and is qualified and has completed training as specified in this paragraph or paragraph (3) of this subsection.

(iii) In order to renew a license to practice pharmacy, during the previous licensure period, a pharmacist engaged in sterile compounding shall complete a minimum of:

(I) two hours of ACPE-accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacist is engaged in compounding low and medium risk sterile preparations; or

(II) four hours of ACPE-accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacist is engaged in compounding high risk sterile preparations.

(3) 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) Prior to September 1, 2015 - initial training and continuing education. 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 paragraph (4)(D) of this subsection. 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. 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; 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 the:]~~

~~[(a-) 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-) individual is under the direct supervision of and responsible to a pharmacist who has completed training as specified in paragraph (2) of this subsection; and]~~

~~[(c-) supervising pharmacist conducts periodic in-process checks as defined in the pharmacy's policy and procedures; and]~~

~~[(d-) supervising pharmacist conducts a final check.]~~

~~[(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 paragraph (2) of this subsection or this paragraph.]~~

~~[(B) [(C) Initial [Effective September 1, 2015- initial] training and continuing education.~~

~~(i) Pharmacy technicians and pharmacy technician trainees may compound sterile preparations provided the pharmacy technicians and/or pharmacy technician trainees are supervised by a pharmacist as [who has completed the training] specified in paragraph (2) of this subsection[; conducts in-process and final checks; and affixes his or her initials to the appropriate quality control records].~~

~~(ii) 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:~~

~~(-a-) a single course, a minimum of 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a course sponsored by an ACPE accredited provider which provides 40 hours of instruction and experience; or~~

~~(-b-) a training program which is accredited by the American Society of Health-System Pharmacists.~~

~~(II) and~~

~~(-a-) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides sufficient hours of instruction and experience in the facility's sterile compounding processes and procedures. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and~~

~~(-b-) possess knowledge about:~~

~~(-1-) aseptic processing;~~

~~(-2-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;~~

~~(-3-) chemical, pharmaceutical, and clinical properties of drugs;~~

~~(-4-) container, equipment, and closure system selection; and~~

~~(-5-) sterilization techniques.~~

(iii) Individuals enrolled in training programs accredited by the American Society of Health-System Pharmacists may compound sterile preparations in a licensed pharmacy provided the:

(I) 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;

(II) individual is under the direct supervision of and responsible to a pharmacist who has completed training as specified in paragraph (2) of this subsection; and

(III) supervising pharmacist conducts periodic in-process checks as defined in the pharmacy's policy and procedures; and

(IV) supervising pharmacist conducts a final check.

(iv) The required experiential portion of the training programs specified in this subparagraph must be supervised by an individual who is actively engaged in performing sterile compounding, is qualified and has completed training as specified in paragraph (2) of this subsection or this paragraph.

(v) In order to renew a registration as a pharmacy technician, during the previous registration period, a pharmacy technician engaged in sterile compounding shall complete a minimum of:

(I) two hours of ACPE accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacy technician is engaged in compounding low and medium risk sterile preparations; or

(II) four hours of ACPE accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if pharmacy technician is engaged in compounding high risk sterile preparations.

(4) Evaluation and testing requirements.

(A) All pharmacy personnel preparing sterile preparations shall be trained conscientiously and skillfully by expert personnel through multimedia instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations, garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures before beginning to prepare compounded sterile preparations.

(B) All pharmacy personnel preparing sterile preparations shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially followed by:

(i) every 12 months for low- and medium-risk level compounding; and

(ii) every six months for high-risk level compounding.

(C) Pharmacy personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall:

(i) be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies; and

(ii) not be allowed to compound sterile preparations for patient use until passing results are achieved.

(D) The didactic and experiential training shall include instruction, experience, and demonstrated proficiency 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 hazardous drugs, if applicable;

(xi) cleaning procedures; and

(xii) general conduct in the clean room.

(E) The aseptic technique of each person compounding or responsible for the direct supervision of personnel compounding sterile preparations shall be observed and evaluated by expert personnel as satisfactory through written and practical tests, and challenge testing, and such evaluation documented. Compounding personnel shall not evaluate their own aseptic technique or results of their own media-fill challenge testing.

(F) 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 indicate 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 completes the on-site media-fill tests within seven days of commencing work at the pharmacy.

(G) Media-fill tests procedures for assessing the preparation of specific types of sterile preparations shall be representative of the most challenging or stressful conditions encountered by the pharmacy personnel being evaluated and, if applicable, for sterilizing high-risk level compounded sterile preparations.

(H) Media-fill challenge tests simulating high-risk level compounding shall be used to verify the capability of the compounding environment and process to produce a sterile preparation.

(I) Commercially available sterile fluid culture media, such as Soybean-Casein Digest Medium shall be able to promote exponential colonization of bacteria that are most likely to be transmitted to compounding sterile preparations from the compounding personnel and environment. Media-filled vials are generally incubated at 20 to 25 degrees Celsius or at 30 to 35 degrees Celsius for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature. Failure is indicated by visible turbidity in the medium on or before 14 days.

(J) 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.

(K) The pharmacist-in-charge shall ensure that proper hand hygiene and garbing practices of compounding personnel are evaluated prior to compounding, supervising, or verifying sterile preparations intended for patient use and whenever an aseptic media fill is performed.

(i) Sampling of compounding personnel glove fingertips shall be performed for all risk level compounding.

(ii) All compounding personnel shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands).

(iii) Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing in order to assess garbing competency and after completing the media-fill preparation (without applying sterile 70% IPA).

(iv) The visual observation shall be documented and maintained to provide a permanent record and long-term assessment of personnel competency.

(v) All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure no less than three times before initially being allowed to compound sterile preparations for patient use. Immediately after the compounding personnel completes the hand hygiene and garbing procedure (i.e., after donning of sterile gloves and before any disinfecting with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands of the compounding personnel onto agar plates or media test paddles by having the individual lightly touching each fingertip onto the agar. The test plates or test paddles will be incubated for the appropriate incubation period and at the appropriate temperature. Results of the initial gloved fingertip evaluations shall indicate zero colony-forming units (0 CFU) growth on the agar plates or media test paddles, or the test shall be considered a failure. In the event of a failed gloved fingertip test, the evaluation shall be repeated until the individual can successfully don sterile gloves and pass the gloved fingertip evaluation, defined as zero CFUs growth. No preparation intended for patient use shall be compounded by an individual until the results of the initial gloved fingertip evaluation indicate that the individual can competently perform aseptic procedures except that a pharmacist may temporarily supervise pharmacy technicians compounding sterile preparations while waiting for the results of the evaluation for no more than three days.

(vi) Re-evaluation of all compounding personnel shall occur at least annually for compounding personnel who compound low and medium risk level preparations and every six months for compounding personnel who compound high risk level preparations. Results of gloved fingertip tests conducted immediately after compounding personnel complete a compounding procedure shall

indicate no more than 3 CFUs growth, or the test shall be considered a failure, in which case, the evaluation shall be repeated until an acceptable test can be achieved (i.e., the results indicated no more than 3 CFUs growth).

(L) The pharmacist-in-charge shall ensure surface sampling shall be conducted in all ISO classified areas on a periodic basis. Sampling shall be accomplished using contact plates at the conclusion of compounding. The sample area shall be gently touched with the agar surface by rolling the plate across the surface to be sampled.

(5) Documentation of Training. The pharmacy shall maintain a record of the training and continuing education 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 available for inspection by the board and contain the following information:

(A) name of the person receiving the training or completing the testing or media-fill tests;

(B) date(s) of the training, testing, or media-fill challenge testing;

(C) general description of the topics covered in the training or testing or of the process validated;

(D) name of the person supervising the training, testing, or media-fill challenge testing; and

(E) 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:

(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 (6)(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 (6)(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 or for office use provided the following conditions are met:

(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet individual 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 individual patient needs the particular strength or dosage form of the preparation or why the preparation for office use is needed in 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 preparation 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.

(H) Compounded sterile preparations, including hazardous drugs and radiopharmaceuticals, shall be prepared only under

conditions that protect the pharmacy personnel in the preparation and storage areas.

(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 in this paragraph.

(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 using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the compounded sterile preparation.

(III) Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

(IV) For a low-risk preparation, in the absence of passing a [direct] sterility test [testing results or appropriate information sources that justify different limits,] the storage periods cannot [may not] exceed the following periods: before administration the compounded sterile preparation is stored properly and are exposed for not more than 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 between minus 25 degrees Celsius and minus 10 degrees Celsius. 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 particles.

(II) Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluent solution to compound drug admixtures and nutritional solutions.

(B) Low-Risk Level compounded sterile preparations with 12-hour or less beyond-use date. Low-risk level compounded sterile preparations are those compounded pursuant to a physician's order for a specific patient under all of the following conditions.

(i) The compounded sterile preparations are compounded in compounding aseptic isolator or compounding aseptic containment isolator that does not meet the requirements described in paragraph (7)(C) or (D) of this subsection (relating to Primary Engineering Control Device) or the compounded sterile preparations are compounded in laminar airflow workbench or a biological safety cabinet that cannot be located within the buffer area.

(ii) The primary engineering control device shall be certified and maintain ISO Class 5 for exposure of critical sites and shall be located in a segregated compounding area restricted to sterile compounding activities that minimizes the risk of contamination of the compounded sterile preparation.

(iii) The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation.

(iv) For a low-risk preparation compounded as described in clauses (i) - (iii) of this subparagraph, administration of such compounded sterile preparations must commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less. However, the administration of sterile radiopharmaceuticals, with documented testing of chemical stability, may be administered beyond 12 hours of preparation.

(C) 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 passing a [direct] sterility test [testing results] the storage periods cannot [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 9 days at a cold temperature, and for 45 days in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius.

(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 more than three 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.

(D) 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 not intended for sterile routes of administration (e.g., oral) are incorporated or a non-sterile device is employed before terminal sterilization.

(II) Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour:

(-a) sterile contents of commercially manufactured products;

(-b) CSPs that lack effective antimicrobial preservatives; and

(-c) sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.

(III) Compounding personnel are improperly garbed and gloved.

(IV) Non-sterile water-containing preparations are exposed no more than 6 hours before being sterilized.

(V) 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.

(VI) For a sterilized high-risk level preparation, in the absence of passing a sterility test, 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 between minus 25 degrees Celsius and minus 10 degrees Celsius.

(VII) All non-sterile measuring, mixing, and purifying devices are rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for high-risk compounding. All high-risk compounded sterile solutions subjected to terminal sterilization are prefiltered by passing through a filter with a nominal pore size 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 with a sterile 0.2 micrometer or 0.22 micrometer nominal pore size filter 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 for more than one hour.

(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, such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the compounded sterile preparation under low-risk level conditions would subject the patient to additional risk due to delays in therapy. Compounded sterile preparations are exempted from the requirements described in this paragraph for low-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, from the manufacturers' original containers and not more than two entries into any one container or package of sterile infusion solution or administration container/device.

(B) Unless required for the preparation, the compounding procedure occurs continuously without delays or interruptions and does not exceed 1 hour.

(C) During preparation, aseptic technique is followed and, if not immediately administered, the finished compounded sterile preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter of biological fluids, mix-ups with other compounded sterile preparations, and direct contact of outside surfaces.

(D) Administration begins not later than one hour following the completion of preparing the compounded sterile preparation.

(E) 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.

(F) 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.

(G) Hazardous drugs shall not be prepared as immediate use compounded sterile preparations.

(4) Single-dose and multiple dose containers.

(A) Opened or needle punctured single-dose containers, such as bags bottles, syringes, and vials of sterile products shall be used within one hour if opened in worse than ISO Class 5 air quality. Any remaining contents must be discarded.

(B) Single-dose containers, including single-dose large volume parenteral solutions and single-dose vials, exposed to ISO Class 5 or cleaner air may be used up to six hours after initial needle puncture.

(C) Opened single-dose fusion sealed containers shall not be stored for any time period.

(D) Multiple-dose containers may be used up to 28 days after initial needle puncture unless otherwise specified by the manufacturer.

(5) 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 containing USP Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding--Nonsterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding; and

(D) any additional USP/NF chapters applicable to the practice of the pharmacy (e.g., USP Chapter 800, Hazardous Drugs--Handling in Healthcare Settings, USP Chapter 823, Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses).

(6) Environment. Compounding facilities shall be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.

(A) Low and Medium Risk Preparations. A pharmacy that prepares low- and medium-risk preparations shall have a clean room for the compounding of sterile preparations that is constructed to minimize the opportunities for particulate and microbial contamination. The clean room shall:

(i) be clean, well lit, and of sufficient size to support sterile compounding activities;

(ii) be maintained at a temperature of 20 degrees Celsius or cooler and at a humidity below 60% [~~a comfortable temperature (e.g., 20 degrees Celsius or cooler) allowing compounding personnel to perform flawlessly when attired in the required aseptic compounding garb~~];

(iii) be used only for the compounding of sterile preparations;

(iv) be designed such that hand sanitizing and gowning occurs outside the buffer area but allows hands-free access by compounding personnel to the buffer area;

(v) have non-porous and washable floors or floor covering to enable regular disinfection;

(vi) be ventilated in a manner to avoid disruption from the HVAC system and room cross-drafts;

(vii) have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices (e.g., coved), non-shedding and resistant to damage by disinfectant agents;

(viii) have junctures of ceilings to walls coved or caulked to avoid cracks and crevices;

(ix) have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning;

(x) 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 clean room. A Class B pharmacy may use low-linting absorbent materials in the primary engineering control device;

(xi) contain an ante-area that contains a sink with hot and cold running water that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination. A Class B pharmacy may have a sink with hot and cold running water that enables hands-free use with a closed system of soap dispensing immediately outside the ante-area if antiseptic hand cleansing is performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations once inside the ante-area; and

(xii) contain a buffer area. The following is applicable for the buffer area.

(I) There shall be some demarcation designation that delineates the ante-area from the buffer area. The demarcation shall be such that it does not create conditions that could adversely affect the cleanliness of the area.

(II) 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.

(III) A buffer area that is not physically separated from the ante-area 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.

(IV) The buffer area shall not contain sources of water (i.e., sinks) or floor drains other than distilled or sterile water introduced for facilitating the use of heat block wells for radiopharmaceuticals.

(B) High-risk Preparations.

(i) In addition to the requirements in subparagraph (A) of this paragraph, when high-risk preparations are compounded, the primary engineering control shall be located in a buffer area 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.

(ii) Presterilization procedures for high-risk level compounded sterile preparations, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.

(C) Automated compounding device.

(i) General. 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 daily basis, based on the manufacturer's recommendations, and review the results at least weekly.

(ii) Loading bulk drugs into automated compounding devices.

(I) Automated compounding device may be loaded with bulk 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 compounding device 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 drugs into an automated compounding device shall be maintained to show:

(-a) name of the drug, strength, and dosage form;

(-b) manufacturer or distributor;

(-c) manufacturer's lot number;

(-d) manufacturer's expiration date;

(-e) quantity added to the automated compounding device;

(-f) date of loading;

(-g) name, initials, or electronic signature of the person loading the automated compounding device; and

(-h) name, initials, or electronic signature of the responsible pharmacist.

(IV) The automated compounding device 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.

(D) Hazardous drugs. If the preparation is hazardous, the following is also applicable.

(i) Hazardous drugs shall be prepared only under conditions that protect personnel during preparation and storage.

(ii) Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure.

(iii) All personnel involved in the compounding of hazardous drugs shall wear appropriate protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and appropriate gloving at all times when handling hazardous drugs, including receiving, distribution, stocking, inventorying, preparation, for administration and disposal.

(iv) Appropriate safety and containment techniques for compounding hazardous drugs shall be used in conjunction with aseptic techniques required for preparing sterile preparations.

(v) Disposal of hazardous waste shall comply with all applicable local, state, and federal requirements.

(vi) Prepared doses of hazardous drugs must be dispensed, labeled with proper precautions inside and outside, and distributed in a manner to minimize patient contact with hazardous agents.

(E) Blood-labeling procedures. When compounding activities require the manipulation of a patient's blood-derived material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be performed in a ISO Class 5 biological safety cabinet located in a buffer area and shall be clearly separated from routine material-handling procedures and equipment used in preparation activities to avoid any cross-contamination. The preparations shall not require sterilization.

(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 areas, ante-areas, and segregated compounding 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 at the beginning of each work shift, before each batch preparation is started, when there are spills, and when surface contamination is known or suspected resulting from procedural breaches, and every 30 minutes during continuous compounding of individual compounded sterile preparations, unless a particular compounding procedure requires more than 30 minutes to complete, in which case, the direct compounding area is to be cleaned immediately after the compounding activity is completed.

(iii) Before compounding is performed, all items shall be removed from the direct and contiguous compounding areas and all surfaces are cleaned by removing loose material and residue from spills, followed by an application of a residue-free disinfecting agent (e.g., IPA), which is allowed to dry before compounding begins. In a Class B pharmacy, objects used in preparing sterile radiopharmaceuticals (e.g., dose calibrator) which cannot be reasonably removed from the compounding area shall be sterilized with an application of a residue-free disinfection agent.

(iv) Work surfaces in the buffer areas and ante-areas, as well as segregated compounding areas, shall be cleaned and disinfected at least daily. Dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 air quality.

(v) Floors in the buffer area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent at least once daily when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs. It is incumbent on compounding personnel to ensure that such cleaning is performed properly.

(vi) In the buffer area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly. Cleaning and disinfecting agents shall be used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues.

(vii) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer area and ante-area, but only in that order. If cleaning materials are reused, procedures shall be developed that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bio-burden of the area being cleaned.

(viii) Supplies and equipment removed from shipping cartons must be wiped with a disinfecting agent, such as sterile IPA. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes. However, if sterile supplies are received in sealed pouches, the pouches may be removed as the supplies are introduced into the ISO Class 5 area without the need to disinfect the individual sterile supply items. No shipping or other external cartons may be taken into the buffer area or segregated compounding area.

(ix) Storage shelving emptied of all supplies, walls, and ceilings are cleaned and disinfected at planned intervals, monthly, if not more frequently.

(x) Cleaning must be done by personnel trained in appropriate cleaning techniques.

(xi) Proper documentation and frequency of cleaning must be maintained and shall contain the following:

(I) date and time of cleaning;

(II) type of cleaning performed; and

(III) name of individual who performed the cleaning.

(G) Security requirements. The pharmacist-in-charge 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 preparations 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 and in §291.15 of this title (relating to Storage of Drugs).

(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) When assigning a beyond-use date, compounding personnel shall consult and apply drug-specific and general stability documentation and literature where available, and they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy.

(IV) The sterility and storage and stability beyond-use date for attached and activated container pairs of drug products for intravascular administration shall be applied as indicated by the manufacturer.

(7) Primary engineering control device. The pharmacy shall prepare sterile preparations in a primary engineering control device (PEC), such as a laminar air flow hood, biological safety cabinet, compounding aseptic isolator (CAI), or compounding aseptic containment isolator (CACI) which is capable of maintaining at least ISO Class 5 conditions for 0.5 micrometer particles while compounding sterile preparations.

(A) Laminar air flow hood. If the pharmacy is using a laminar air flow hood as its PEC, the laminar air flow hood shall:

(i) be located in the buffer area 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;

(ii) be certified by a qualified independent contractor according to the appropriate Controlled Environment Testing Association (CETA) standard (CAG-003-2006) for operational efficiency at least every six months and whenever the device or room is relocated or altered or major service to the facility is performed;

(iii) 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; and

(iv) be located in a buffer area that has a minimum differential positive pressure of 0.02 to 0.05 inches water column. A buffer area that is not physically separated from the ante-area 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.

(B) Biological safety cabinet.

(i) If the pharmacy is using a biological safety cabinet as its PEC for the preparation of hazardous sterile compounded preparations, the biological safety cabinet shall be a Class II or III vertical flow biological safety cabinet located in an ISO Class 7 area that is physically separated from other preparation areas. The area for preparation of sterile chemotherapeutic preparations shall:

(I) have not less than 0.01 inches water column negative pressure to the adjacent positive pressure ISO Class 7 or better ante-area; and

(II) have a pressure indicator that can be readily monitored for correct room pressurization.

(ii) Pharmacies that prepare a low volume of hazardous drugs, are not required to comply with the provisions of clause (i) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., closed-system vial transfer device within a BSC or CACI that is located in a non-negative pressure room).

(iii) If the pharmacy is using a biological safety cabinet as its PEC for the preparation of non-hazardous sterile compounded preparations, the biological safety cabinet shall:

(I) be located in the buffer area 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;

(II) be certified by a qualified 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 whenever the device or room is relocated or altered or major service to the facility is performed, in accordance with the manufacturer's specifications and test procedures specified in the Institute of Environmental Sciences and Technology (IEST) document IEST-RP-CC002.3;

(III) 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; and

(IV) be located in a buffer area that has a minimum differential positive pressure of 0.02 to 0.05 inches water column.

(C) Compounding aseptic isolator.

(i) If the pharmacy is using a compounding aseptic isolator (CAI) as its PEC, the CAI shall provide unidirectional airflow within the main processing and antechambers, and be placed in an ISO Class 7 buffer area unless the isolator meets all of the following conditions:

(I) 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.

(II) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site must maintain ISO Class 5 levels during compounding operations.

(III) The CAI must be validated according to CETA CAG-002-2006 standards.

(IV) The pharmacy shall maintain documentation from the manufacturer that the isolator meets this standard when located in worse than ISO Class 7 environments.

(ii) If the isolator meets the requirements in clause (i) of this subparagraph, the CAI may be placed in a non-ISO classified area of the pharmacy; however, the area shall be segregated from other areas of the pharmacy and shall:

(I) be clean, well lit, and of sufficient size;

(II) be used only for the compounding of low- and medium-risk, non-hazardous sterile preparations;

(III) be located in an area of the pharmacy with non-porous and washable floors or floor covering to enable regular disinfection; and

(IV) be an area in which the CAI is placed in a manner as to avoid conditions that could adversely affect its operation.

(iii) In addition to the requirements specified in clauses (i) and (ii) of this subparagraph, if the CAI is used in the compounding of high-risk non-hazardous preparations, the CAI shall be placed in an area or room with at least ISO 8 quality air so that high-risk powders weighed in at least ISO-8 air quality conditions, compounding utensils for measuring and other compounding equipment are not exposed to lesser air quality prior to the completion of compounding and packaging of the high-risk preparation.

(D) Compounding aseptic containment isolator.

(i) If the pharmacy is using a compounding aseptic containment isolator as its PEC for the preparation of low- and medium-risk hazardous drugs, the CACI shall be located in a separate room away from other areas of the pharmacy and shall:

(I) provide at least 0.01 inches water column negative pressure compared to the other areas of the pharmacy;

(II) provide unidirectional airflow within the main processing and antechambers, and be placed in an ISO Class 7 buffer area, unless the CACI 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 CACI must be validated according to CETA CAG-002-2006 standards.

(-d-) The pharmacy shall maintain documentation from the manufacturer that the isolator meets this standard when located in worse than ISO Class 7 environments.

(ii) If the CACI meets all conditions specified in clause (i) of this subparagraph, the CACI shall not be located in the same room as a CAI, but shall be located in a separate room in the

pharmacy, that is not required to maintain ISO classified air. The room in which the CACI is located shall provide a minimum of 0.01 inches water column negative pressure compared with the other areas of the pharmacy and shall meet the following requirements:

(I) be clean, well lit, and of sufficient size;

(II) be maintained at a temperature of 20 degrees Celsius or cooler and a humidity below 60% [~~comfortable temperature (e.g., 20 degrees Celsius or cooler) allowing compounding personnel to perform flawlessly when attired in the required aseptic compounding garb~~];

(III) be used only for the compounding of hazardous sterile preparations;

(IV) be located in an area of the pharmacy with walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices, non-shedding and resistant to damage by disinfectant agents; and

(V) have non-porous and washable floors or floor covering to enable regular disinfection.

(iii) If the CACI is used in the compounding of high-risk hazardous preparations, the CACI shall be placed in an area or room with at least ISO 8 quality air so that high-risk powders, weighed in at least ISO-8 air quality conditions, are not exposed to lesser air quality prior to the completion of compounding and packaging of the high-risk preparation.

(8) Additional 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 preparations are stored in the refrigerator;

(B) a calibrated system or device to monitor the temperature where bulk chemicals are stored;

(C) a temperature-sensing mechanism suitably placed in the controlled temperature storage space to reflect accurately the true temperature;

(D) 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;

(E) 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;

(F) appropriate disposal containers for used needles, syringes, etc., and if applicable, hazardous waste from the preparation of hazardous drugs and/or biohazardous waste;

(G) appropriate packaging or delivery containers to maintain proper storage conditions for sterile preparations;

(H) infusion devices, if applicable; and

(I) all necessary supplies, including:

(i) disposable needles, syringes, and other supplies for aseptic mixing;

(ii) disinfectant cleaning solutions;

(iii) sterile 70% isopropyl alcohol;

(iv) sterile gloves, both for hazardous and non-hazardous drug compounding;

(v) sterile alcohol-based or water-less alcohol based surgical scrub;

(vi) hand washing agents with bactericidal action;

(vii) disposable, lint free towels or wipes;

(viii) appropriate filters and filtration equipment;

(ix) hazardous spill kits, if applicable; and

(x) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.

(9) 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 other than sterile radiopharmaceuticals, 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 (7)(G) of this subsection;

(B) Batch. If the sterile preparation 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.

(10) 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. This paragraph does not apply to the preparation of radiopharmaceuticals.

(11) 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. This paragraph does not apply to the preparation of radiopharmaceuticals.

(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;

(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; and

(iii) reports of adverse events with a compounded sterile preparation are reviewed promptly and thoroughly to correct and prevent future occurrences.

(12) 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 preparation 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.

(13) 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 and implemented 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, including rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infection, that may adversely affect the safety or quality of a drug preparation being compounded shall be excluded from working in ISO Class 5, ISO Class 7, and ISO Class 8 compounding areas until the condition is remedied.

(ii) Before entering the buffer 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 or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of personal protective equipment (e.g., fit of gloves and cuffs of sleeves).

(iii) The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed.

(iv) Personnel shall 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 or when preparing hazardous drugs.

(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 ante-area. Hands and forearms to the elbows shall be completely dried using lint-free disposable towels, an electronic hands-free hand dryer, or a HEPA filtered hand dryer.

(III) After completion of hand washing, personnel shall don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclosed at the neck.

(IV) Once inside the buffer area or segregated compounding area, and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations. Hands shall be allowed to dry thoroughly before donning sterile gloves.

(V) Sterile gloves that form a continuous barrier with the gown shall be the last item donned before compounding be-

gins. Sterile gloves shall be donned using proper technique to ensure the sterility of the glove is not compromised while donning. The cuff of the sterile glove shall cover the cuff of the gown at the wrist. When preparing hazardous preparations, the compounder shall double glove or shall use single gloves ensuring that the gloves are sterile powder-free chemotherapy-rated gloves. Routine application of sterile 70% IPA shall occur throughout the compounding day and whenever non-sterile surfaces are touched.

(vi) When compounding personnel shall temporarily exit the buffer area during a work shift, the exterior gown, if not visibly soiled, may be removed and retained in the 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 shall be replaced with new ones before re-entering the buffer area along with performing proper hand hygiene.

(vi) During high-risk compounding activities that precede terminal sterilization, such as weighing and mixing of non-sterile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 environment. Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 shall re-garb personal protective equipment along with washing their hands properly, performing antiseptic hand cleansing with a sterile 70% IPA-based or another suitable sterile alcohol-based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7 buffer area.

(vii) When compounding aseptic isolators or compounding aseptic containment isolators are the source of the ISO Class 5 environment, at the start of each new compounding procedure, a new pair of sterile gloves shall be donned within the CAI or CACI. In addition, the compounding personnel should follow the requirements as specified in this subparagraph, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any components of personal protective equipment or cleansing are not required.

(14) 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 preparation 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, except for sterile radiopharmaceuticals, 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 preparations. 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 a minimum of 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 a minimum of 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 non-sterile commercially available Soybean-Casein Digest Medium in 100 milliliters of non-bacteriostatic water to make a 3% non-sterile solution.

(-b-) Draw 25 milliliters of the medium into each of three 30-milliliter sterile syringes. Transfer 5 milliliters from each syringe into separate sterile 10-milliliter vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.

(-c-) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron porosity filter unit and a 20-gauge needle to each syringe. Inject the next 10 milliliters from each syringe into three separate 10-milliliter sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20 to 35 degrees Celsius for a minimum of 14 days. Inspect for microbial growth over 14 days as described in Chapter 797 Pharmaceutical Compounding--Sterile Preparations, of the USP/NF.

(III) Filter Integrity Testing. Filters need to undergo testing to evaluate the integrity of filters used to sterilize high-risk preparations, such as Bubble Point Testing or comparable filter integrity testing. Such testing is not a replacement for sterility testing and shall not be interpreted as such. Such test shall be performed after a sterilization procedure on all filters used to sterilize each high-risk preparation or batch preparation and the results documented. The results should be compared with the filter manufacturer's specification for the specific filter used. If a filter fails the integrity test, the preparation or batch must be sterilized again using new unused filters.

(B) Finished preparation release checks and tests.

(i) 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 and longer than six hours at warmer than 8 degrees Celsius 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 before being dispensed or administered.

(ii) All compounded sterile preparations, except for sterile radiopharmaceuticals, 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 dispensed or administered.

(iv) Written procedures for checking compounding accuracy shall be followed for every compounded sterile preparation during preparation, in accordance with pharmacy's policies and procedures, and immediately prior to release, including label accuracy and the accuracy of the addition of all drug products or ingredients used to prepare the finished preparation and their volumes or quantities. A pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(C) Environmental Testing.

(i) Viable and nonviable environmental sampling testing. Environmental sampling shall occur, at a minimum, every six months as part of a comprehensive quality management program and under any of the following conditions:

(I) as part of the commissioning and certification of new facilities and equipment;

(II) following any servicing of facilities and equipment;

(III) as part of the re-certification of facilities and equipment;

(IV) in response to identified problems with end products or staff technique; or

(V) in response to issues with compounded sterile preparations, observed compounding personnel work practices, or patient-related infections (where the compounded sterile preparation is being considered as a potential source of the infection).

(ii) Total particle counts. Certification that each ISO classified area (e.g., ISO Class 5, 7, and 8), is within established guidelines shall be performed no less than every six months and whenever the equipment is relocated or the physical structure of the buffer area or ante-area has been altered. All certification records shall be maintained and reviewed to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and air changes per hour. Testing shall be performed by qualified operators using current, state-of-the-art equipment, with results of the following:

(I) ISO Class 5 - not more than 3520 particles 0.5 micrometer and larger size per cubic meter of air;

(II) ISO Class 7 - not more than 352,000 particles of 0.5 micrometer and larger size per cubic meter of air for any buffer area; and

(III) ISO Class 8 - not more than 3,520,000 particles of 0.5 micrometer and larger size per cubic meter of air for any ante-area.

(iii) Pressure differential monitoring. A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 or ISO Class 8 and the general pharmacy area shall not be less than 0.02 inch water column.

(iv) Sampling plan. An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas and in the segregated compounding areas at greatest risk of contamination. The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.

(v) Viable air sampling. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments shall be performed by properly trained individuals for all compounding risk levels. For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning. Locations shall include zones of air backwash turbulence within the laminar airflow workbench and other areas where air backwash turbulence may enter the compounding area. For low-risk level compounded sterile preparations within 12-hour or less beyond-use-date prepared in a primary engineering control that maintains an ISO Class 5, air sampling shall

be performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class 5 environment during the certification of the primary engineering control.

(vi) Air sampling frequency and process. Air sampling shall be performed at least every 6 months as a part of the re-certification of facilities and equipment. A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed. At the end of the designated sampling or exposure period for air sampling activities, the microbial growth media plates are recovered and their covers secured and they are inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.

(vii) Compounding accuracy checks. Written procedures for checking compounding accuracy shall be followed for every compounded sterile preparation during preparation and immediately prior to release, including label accuracy and the accuracy of the addition of all drug products or ingredients used to prepare the finished preparation and their volumes or quantities. 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.

(15) 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 USP Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding-Non-sterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations, USP Chapter 800, Hazardous Drugs--Handling in Healthcare Settings, USP Chapter 823, Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses, USP Chapter 1160, Pharmaceutical Calculations in Prescription Compounding, and USP Chapter 1163, Quality Assurance in Pharmaceutical 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 identity, purity, strength, and sterility of ingredients and components of compounded sterile preparations cannot be confirmed such ingredients and components shall be discarded immediately. Any compounded sterile preparation that fails sterility testing following sterilization by one method (e.g., filtration) is to be discarded and not subjected to a second method of sterilization.

(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. Any testing, cleaning, procedures, or other activities required in this subsection shall be documented and such documentation shall be maintained by the pharmacy.

(1) Maintenance of records. Every record required under this section must 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 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 and time 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) written or electronic signature or initials of the pharmacist or pharmacy technician or pharmacy technician trainee performing the compounding;

(iv) written or electronic signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting final checks of compounded pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the compounding function;

(v) the quantity in units of finished preparation 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 Sterile Compounded Preparations

(1) General.

(A) A pharmacy may compound, dispense, deliver, and distribute a compounded sterile preparation as specified in Subchapter D, Texas Pharmacy Act Chapter 562.

(B) A Class A-S 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 or Class C-S pharmacy.

(C) A Class C-S 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-S pharmacy has compounded for other Class C or Class C-S pharmacies under common ownership.

(D) To compound 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.

(E) This subsection does not apply to Class B pharmacies compounding sterile radiopharmaceuticals that are furnished for departmental or physicians' use if such authorized users maintain a Texas radioactive materials license.

(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 to a veterinarian 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 an 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 preparations 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 an institutional 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 institutional 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 an institutional 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 institutional 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 pharmacy licensed to compound sterile preparations for administration to a patient in such a manner as to be able to provide an 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 institutional 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 procedures for the recall of any compounded sterile preparation provided to a patient, to a practitioner for office use, or a pharmacy for administration. Written procedures shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.

(2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.

(3) In the event of a recall, the pharmacist-in-charge shall ensure that:

(A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;

(B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;

(C) the board is notified of the recall, in writing, not later than 24 hours after the recall is issued;

(D) if the preparation is distributed for office use, the Texas Department of State Health Services, Drugs and Medical Devices Group, is notified of the recall, in writing;

(E) the preparation is quarantined; and

(F) the pharmacy keeps a written record of the recall including all actions taken to notify all parties and steps taken to ensure corrective measures.

(4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if there is potential for or confirmed harm to a patient.

(5) A pharmacy that compounds sterile preparations shall notify the board immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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TRD-201600949

Gay Dodson, R. Ph.

Executive Director

Texas State Board of Pharmacy

Earliest possible date of adoption: April 10, 2016

For further information, please call: (512) 305-8026



CHAPTER 297. PHARMACY TECHNICIANS AND PHARMACY TECHNICIAN TRAINEES

22 TAC §297.3, §297.10

The Texas State Board of Pharmacy proposes amendments to §297.3, concerning Registration Requirements, and §297.10, concerning Registration for Military Service Members, Military Veterans, and Military Spouses. The amendments, if adopted, eliminate the provisions allowing individuals who are unable to obtain a social security number to provide an individual taxpayer identification number in lieu of a social security number because a social security number is required in order to process criminal background checks.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Ms. Dodson has determined that, for each year of the first five-year period the rules will be in effect, the public benefit anticipated as a result of enforcing the amendments will ensure individuals applying for a pharmacy technician registration meet the requirements in order to conduct criminal background checks. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with these sections.

Written comments on the amendments may be submitted to Allison Vordenbaumen 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) 305-6778. Comments must be received by 5 p.m., April 25, 2016.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 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 these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§297.3. Registration Requirements.

(a) General.

(1) Individuals who are not registered with the Board may not be employed as or perform the duties of a pharmacy technician or pharmacy technician trainee.

(2) Individuals who have previously applied and registered as a pharmacy technician, regardless of the pharmacy technician's current registration status, may not register as a pharmacy technician trainee.

(3) Individuals who apply and are qualified for both a pharmacy technician trainee registration and a pharmacy technician registration concurrently will not be considered for a pharmacy technician trainee registration.

(b) Registration for pharmacy technician trainees. An individual may register as a pharmacy technician trainee only once and the registration may not be renewed.

(1) Each applicant for pharmacy technician trainee registration shall:

(A) have a high school or equivalent diploma (e.g., GED), or be working to achieve a high school or equivalent diploma. For the purposes of this subparagraph, an applicant for registration may be working to achieve a high school or equivalent diploma for no more than two years;

(B) complete the Texas application for registration that includes the following information:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; [however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number;] and

(iii) any other information requested on the application.

(C) meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and paying the required fees.

(2) Once an applicant has successfully completed all requirements of registration, and the board has determined there are no grounds to refuse registration, the applicant will be notified of registration as a pharmacy technician trainee and of his or her pharmacy technician trainee registration number.

(3) Pharmacy technician trainee registrations expire two years from the date of registration or upon issuance of registration as a registered pharmacy technician, whichever is earlier.

(c) Initial registration for pharmacy technicians.

(1) Each applicant for pharmacy technician registration shall:

(A) have a high school or equivalent diploma (e.g., GED), or be working to achieve a high school or equivalent diploma. For the purpose of this clause, an applicant for registration may be working to achieve a high school or equivalent diploma for no more than two years; and

(B) either have:

(i) taken and passed the Pharmacy Technician Certification Board's National Pharmacy Technician Certification Examination or other examination approved by the board and have a current certification certificate; or

(ii) been granted an exemption from certification by the board as specified in §297.7 of this title (relating to Exemption from Pharmacy Technician Certification Requirements); and

(C) complete the Texas application for registration that includes the following information:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; [however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number;] and

(iii) any other information requested on the application.

(D) meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and paying the required fees; and

(E) pay the registration fee specified in §297.4 of this title (relating to Fees).

(2) Once an applicant has successfully completed all requirements of registration, and the board has determined there are no grounds to refuse registration, the applicant will be notified of registration as a registered pharmacy technician and of his or her pharmacy technician registration number. If the pharmacy technician applicant was registered as a pharmacy technician trainee at the time the pharmacy technician registration issued, the pharmacy technician trainee registration expires.

(d) Renewal.

(1) All applicants for renewal of a pharmacy technician registration shall:

(A) complete the Texas application for registration that includes the following information:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; [however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number;]

(iii) meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs; and

(iv) any other information requested on the application.

(B) pay the renewal fee specified in §297.4 of this title; and

(C) complete 20 contact hours of continuing education per renewal period as specified in §297.8 of this title (relating to Continuing Education).

(2) A pharmacy technician registration expires on the last day of the assigned expiration month.

(3) If the completed application and renewal fee are not received in the board's office on or before the last day of the assigned expiration month, the person's pharmacy technician registration shall expire. A person shall not practice as a pharmacy technician with an expired registration.

(4) If a pharmacy technician registration has expired, the person may renew the registration by paying to the board the renewal fee and a delinquent fee that is equal to the renewal fee as specified in §297.4 of this title.

(5) If a pharmacy technician registration has expired for more than one year, the pharmacy technician may not renew the registration and must complete the requirements for initial registration as specified in subsection (c) of this section.

(6) After review, the board may determine that paragraph (5) of this subsection does not apply if the registrant is the subject of a pending investigation or disciplinary action.

(e) An individual may use the title "Registered Pharmacy Technician" or "Ph.T.R." if the individual is registered as a pharmacy technician in this state.

§297.10. Registration for Military Service Members, Military Veterans, and Military Spouses.

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

(1) Active duty--Current full-time military service in the armed forces of the United States or active duty military service as a member of the Texas military forces, or similar military service of another state.

(2) Armed forces of the United States--The army, navy, air force, coast guard, or marine corps of the United States or a reserve unit of one of those branches of the armed forces.

(3) Military service member--A person who is on active duty.

(4) Military spouse--A person who is married to a military service member.

(5) Military veteran--A person who has served on active duty and who was discharged or released from active duty.

(b) Alternative registration procedure. For the purpose of §55.004, Occupations Code, an applicant for a pharmacy technician registration who is a military service member, military veteran, or military spouse may complete the following alternative procedures for registering as a pharmacy technician.

(1) An applicant who holds a current registration as a pharmacy technician issued by another state but does not have a current PTCB certificate shall meet the requirements for registration as a pharmacy technician trainee as specified in §297.3 of this chapter (relating to Registration Requirements).

(2) An applicant who held a pharmacy technician registration in Texas that expired within the five years preceding the application date who meets the following requirements may be granted a pharmacy technician registration. The applicant:

(A) shall complete the Texas application for registration that includes the following:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; [~~however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number;~~] and

(iii) any other information requested on the application;

(B) shall provide documentation to include:

(i) military identification indicating that the applicant is a military service member, military veteran, or military dependent, if a military spouse; and

(ii) marriage certificate, if the applicant is a military spouse; applicant's spouse is on active duty status;

(C) be exempt from the application fees paid to the board set forth in §297.4(a) and (b)(2) of this chapter;

(D) shall meet all necessary requirements in order for the board to access the criminal history records information, including submitting fingerprint information and such criminal history check does not reveal any charge or conviction for a crime that §281.64 of this title (relating to Sanctions for Criminal Offenses) indicates a sanction of denial, revocation, or suspension; and

(E) is not required to have a current PTCB certificate.

(c) Expedited registration procedure. For the purpose of §55.005, Occupations Code, an applicant for a pharmacy technician registration who is a military service member, military veteran or military spouse and who holds a current registration as a pharmacy technician issued by another state or who held a pharmacy technician registration in Texas that expired within the five years preceding the application date may complete the following expedited procedures for registering as a pharmacy technician.

(1) The applicant shall:

(A) have a high school or equivalent diploma (e.g., GED), or be working to achieve a high school or equivalent diploma. For the purpose of this clause, an applicant for registration may be working to achieve a high school or equivalent diploma for no more than two years; and

(B) have taken and passed the Pharmacy Technician Certification Board's National Pharmacy Technician Certification Examination or other examination approved by the board and have a current certification certificate; and

(C) complete the Texas application for registration that includes the following information:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; [~~however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number;~~] and

(iii) any other information requested on the application.

(D) meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and paying the required fees;

(E) shall be exempt from the registration fee as specified in §297.4(b)(2) of this chapter (relating to Fees).

(2) Once an applicant has successfully completed all requirements of registration, and the board has determined there are no grounds to refuse registration, the applicant will be notified of registration as a registered pharmacy technician and of his or her pharmacy technician registration number.

(3) All applicants for renewal of an expedited pharmacy technician registration issued to a military service member, military veteran, or military spouse shall comply with the renewal procedures

as specified in §297.3 of this chapter (relating to Registration Requirements).

(d) License renewal. As specified in §55.003, Occupations Code, a military service member who holds a pharmacy technician registration is entitled to two years of additional time to complete any requirements related to the renewal of the military service member's registration as follows:

(1) A military service member who fails to renew their pharmacy technician registration in a timely manner because the individual was serving as a military service member shall submit to the board:

(A) name, address, and registration number of the pharmacy technician;

(B) military identification indicating that the individual is a military service member; and

(C) a statement requesting up to two years of additional time to complete the renewal.

(2) A military service member specified in paragraph (1) of this subsection shall be exempt from fees specified in §297.3(d)(4) of this chapter (relating to Registration Requirements).

(3) A military service member specified in paragraph (1) of this subsection is entitled to two additional years of time to complete the continuing education requirements specified in §297.8 of this title (relating to Continuing Education Requirements).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 26, 2016.

TRD-201600950

Gay Dodson, R. Ph.

Executive Director

Texas State Board of Pharmacy

Earliest possible date of adoption: April 10, 2016

For further information, please call: (512) 305-8026



TITLE 34. PUBLIC FINANCE

PART 1. COMPTROLLER OF PUBLIC ACCOUNTS

CHAPTER 3. TAX ADMINISTRATION

SUBCHAPTER HH. MIXED BEVERAGE TAXES

34 TAC §3.1002

The Comptroller of Public Accounts proposes an amendment to §3.1002, concerning mixed beverage sales tax. This section implements Senate Bill 31, 84th Legislature, 2015, which added Tax Code, §151.310(c-1) to provide an exemption from sales and use tax for volunteer fire departments' fundraising sales and auctions, effective May 28, 2015. Although Senate Bill 31 did not amend Tax Code, Chapter 183, Subchapter B-1 (Mixed Beverage Sales Tax), pursuant to Tax Code, §183.043 (Applicability of Other Law), mixed beverage sales tax is administered, col-

lected, and enforced in the same manner as the tax under Tax Code, Chapter 151 (Limited Sales, Excise, and Use Tax) is administered, collected, and enforced. Therefore, the exemption from collecting sales tax on fundraising sales or auctions for volunteer fire departments in Tax Code, §151.310(c-1) also applies to the collection of mixed beverage sales tax.

Subsection (f)(5) is amended to add language that the exemption is effective May 28, 2015, and that a previous exemption from mixed beverage sales tax at fundraising sales and auctions expired on September 1, 2014.

Tom Currah, 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. Currah 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 by conforming the rule to current state statutes. This 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 rule.

Comments on the proposal may be submitted to Teresa G. Bostick, Director Tax Policy Division, P.O. Box 13528, Austin, Texas 78711-3528. Comments must be received no later than 30 days from the date of publication of the proposal in the *Texas Register*.

The 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 amendment implements Tax Code, §151.310 (Religious, Educational, and Public Service Organizations) and §183.043 (Applicability of Other Law).

§3.1002. *Mixed Beverage Sales Tax.*

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

(1) Alcoholic beverage--This term has the same meaning as assigned by §3.1001 of this title (relating to Mixed Beverage Gross Receipts Tax).

(2) Complimentary alcoholic beverage--This term has the same meaning as assigned by §3.1001 of this title.

(3) Governmental entity--An organization that is exempted from sales and use tax otherwise imposed on their purchases under Tax Code, Chapter 151 (Limited Sales, Excise, and Use Taxes), by operation of Tax Code, §151.309 (Governmental Entities).

(4) Nonprofit organization--An organization that is exempted from the sales and use tax imposed under Tax Code, Chapter 151, by operation of Tax Code, §151.310(a) (Religious, Educational, and Public Service Organizations).

(5) Permittee--This term has the same meaning as assigned by §3.1001 of this title.

(b) Mixed beverage sales tax. A tax at a rate of 8.25% is imposed on each alcoholic beverage sold, prepared, or served by a permittee, and on ice and each nonalcoholic beverage sold, prepared, or served by a permittee to be mixed with alcohol and consumed on the permittee's premises. The sales price of each item on which mixed

beverage sales tax is imposed includes, but is not limited to, those items identified in §3.1001(c) of this title. Those items identified in §3.1001(f)(1) - (7) of this title are excluded from the sales price of items on which mixed beverage sales tax is imposed. Mixed beverage sales tax is imposed in addition to the mixed beverage gross receipts tax imposed under Tax Code, Chapter 183, Subchapter B.

(c) Administration, collection, and enforcement of mixed beverage sales tax.

(1) Except as otherwise provided in this paragraph, mixed beverage sales tax is administered, collected, and enforced in the same manner as sales and use tax is administered, collected, and enforced in Tax Code, Chapter 151, except:

(A) a permittee may not deduct or withhold any amount of taxes collected as reimbursement for the cost of collecting the tax, pursuant to Tax Code, §151.423 (Reimbursement to Taxpayer for Tax Collection); and

(B) a permittee may not receive a discount for prepaying the tax, pursuant to Tax Code, §151.424 (Discount for Prepayments).

(2) Tax due is debt of the purchaser. Mixed beverage sales tax is a debt of the purchaser to the permittee until collected.

(3) Tax-included sales price. The total amount shown on a customer's sales invoice, billing, service check, ticket, or other receipt for sales that are subject to mixed beverage sales tax is presumed to be the sales price, without tax included. Contracts, bills, invoices, or other receipts that merely state that "all taxes" are included are not sufficient to relieve either the customer or the permittee of their tax responsibilities on the transaction. The permittee may overcome the presumption by using the permittee's records to show that tax was included in the sales price.

(4) Record-keeping requirements. Permittees are responsible for creating and maintaining records of purchases and sales as required by §3.1001(j) - (m) and (o) of this title.

(5) Bad debts. The exclusion of bad debts from the mixed beverage gross receipts tax base, as established in §3.1001(n) of this title, does not apply to mixed beverage sales tax. Bad debt deductions from mixed beverage sales tax are treated in the same manner as bad debt deductions from sales tax. For more information on bad debt deductions from sales tax, refer to §3.302 of this title (relating to Accounting Methods, Credit Sales, Bad Debt Refunds, Repossession Refunds, Interest on Sales Tax, and Trade-Ins).

(d) Separate tax disclosure statement.

(1) A permittee may include on a customer's sales invoice, billing, service check, ticket, or other receipt that includes an item subject to mixed beverage sales tax:

(A) a statement that mixed beverage sales tax is included in the sales price;

(B) a separate statement of the amount of mixed beverage gross receipts tax to be paid by the permittee on that sale;

(C) a separate statement of the amount of mixed beverage sales tax imposed on that item;

(D) a statement of the combined amount of mixed beverage gross receipts tax and mixed beverage sales tax to be paid on that item; or

(E) a statement of the combined amount of mixed beverage sales tax and sales and use tax imposed under Tax Code, Chapter

151, to be paid on all items listed on that sales invoice, billing, service check, ticket, or other receipt.

(2) Mixed beverage gross receipts tax cannot be charged to or paid by the customer. A receipt with a statement of the combined amount of mixed beverage gross receipts tax and mixed beverage sales tax provided in paragraph (1)(D) of this subsection must clearly show that the customer is not being charged mixed beverage gross receipts tax.

(3) For each receipt with a statement of the combined amount of mixed beverage sales tax and sales and use tax, as provided in paragraph (1)(E) of this subsection, the permittee's books and records must clearly show the amount of mixed beverage sales tax and sales and use tax on each sale of alcohol.

(4) Examples of disclosure of tax statements.
Figure: 34 TAC §3.1002(d)(4) (No change.)

(e) Complimentary beverages. A permittee owes sales and use tax, as imposed by Tax Code, Chapter 151, on the purchase of alcoholic beverages, ice, and nonalcoholic beverages that are ingredients of a complimentary alcoholic beverage or that are served or provided by the permittee, without any consideration from the customer, to be mixed with a complimentary alcoholic beverage and consumed on the permittee's premises. The permittee also owes sales and use tax on taxable items that are furnished with a complimentary alcoholic beverage, such as napkins and straws.

(f) Exemptions; governmental entities; nonprofit organizations; university and student organizations; volunteer fire departments; temporary permit.

(1) Governmental entity exempt on purchase of alcohol. A governmental entity can claim an exemption from mixed beverage sales tax on the purchase of alcohol in the same manner as a governmental entity can claim exemption from the payment of sales and use tax on the purchase of alcohol under Tax Code, §151.309.

(2) Purchase of alcohol by nonprofit organization not exempt. A nonprofit organization cannot claim an exemption from the mixed beverage sales tax on the purchase of alcohol. In addition, except as provided in this subsection, a nonprofit organization is responsible for collecting mixed beverage sales tax on the sale, preparation, or service of alcoholic beverages to the same extent that the organization is responsible for paying mixed beverage gross receipts tax on such beverages. For more information, refer to §3.1001(e) of this title.

(3) Nonprofit organizations; fundraising events.

(A) The sale, preparation, or service of alcohol is exempt from mixed beverage sales tax when sold by a nonprofit organization that qualifies for exemption from sales and use tax under Tax Code, §151.310(a)(1) or (2) during a qualifying fundraising sale or auction authorized by Tax Code, §151.310(c).

(B) Except as provided in subparagraph (A) of this paragraph, the sale, preparation, or service of alcohol by a nonprofit organization that qualifies for exemption from sales and use tax under Tax Code, §151.310(a)(1) or (2) is computed in the same manner as mixed beverage gross receipts tax is computed in §3.1001(e) of this title.

(4) University and college student organizations. The sale, preparation, or service of alcohol is exempt from mixed beverage sales tax when sold by a university or college student organization that is certified as an affiliated organization by a university or college as defined in Education Code, §61.003 (Definitions) during a sale authorized by Tax Code, §151.321 (University and College Student Organizations).

(5) Volunteer fire departments; fundraising events. The sale, preparation, or service of alcohol is exempt from mixed beverage sales tax when sold by a volunteer fire department that qualifies for exemption from sales and use tax under Tax Code, §151.310(a)(4) during a qualifying fundraising sale or auction authorized by Tax Code, §151.310(c-1). This exemption is effective May 28, 2015. A previous exemption from mixed beverage sales tax on the sale, preparation, or service of alcohol when sold by volunteer fire departments at fundraising events expired [expires] on September 1, 2014.

(6) Temporary mixed beverage permit required. Nonprofit organizations, university or college student organizations, and volunteer fire departments must hold a daily temporary mixed beverage permit or daily temporary private club permit, issued by the Texas Alcoholic Beverage Commission, in order to sell alcoholic beverages and claim an exemption from mixed beverage sales tax on those sales pursuant to paragraphs (3) - (5) of this subsection.

(7) Governmental entities and nonprofit organizations owe mixed beverage gross receipts tax. A governmental entity or nonprofit organization is not exempt from the payment of mixed beverage gross receipts tax on receipts from the sale, service, or preparation of alcoholic beverages. This includes sales of alcohol during any fundraising sale or auction. For more information, refer to §3.1001(e) of this title.

(g) Lump-sum charges that include alcoholic beverages and additional items together for a single price.

(1) Permittees shall compute mixed beverage sales tax on alcoholic beverages that are served together with meals for a single charge in the same manner as mixed beverage gross receipts tax is computed in §3.1001(c)(1)(D) of this title.

(2) Permittees shall compute mixed beverage sales tax on alcoholic beverages that are served at private clubs, special events, or functions in the same manner as mixed beverage gross receipts tax is computed in §3.1001(d) of this title.

(h) Inventory used in cooking. Alcoholic beverages used in cooking are exempt from both mixed beverage sales tax under Tax Code, Chapter 183, and sales and use tax under Tax Code, Chapter 151, provided that the permittee follows the record-keeping requirements set out in §3.1001(h) and (l) of this title.

(i) Mixed beverage sales tax reports.

(1) Due dates. Reports and remittances are due on or before the 20th day of the month following the reporting period end date. Reports and remittances due on a Saturday, Sunday, or legal holiday may be submitted on the next business day.

(2) Reporting periods.

(A) Monthly filers. Permittees who have \$1,500 or more in mixed beverage sales tax per quarter to report must file monthly reports.

(B) Quarterly filers. Permittees who have less than \$1,500 in mixed beverage sales tax per quarter to report may file returns quarterly. The quarterly reporting periods end on March 31, June 30, September 30, and December 31.

(3) Each permittee must file a mixed beverage sales tax report even if no sales or services of alcoholic beverages were made during the report period. The Texas Mixed Beverage Sales Tax report is due in addition to the Texas Mixed Beverage Gross Receipts Tax report to be filed under Tax Code, Chapter 183, Subchapter B, and the Texas Sales and Use Tax report required to be filed under Tax Code, Chapter 151.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 26, 2016.

TRD-201600972

Don Neal

Chief Deputy General Counsel

Comptroller of Public Accounts

Earliest possible date of adoption: April 10, 2016

For further information, please call: (512) 475-0387

◆ ◆ ◆
TITLE 37. PUBLIC SAFETY AND CORRECTIONS

PART 1. TEXAS DEPARTMENT OF PUBLIC SAFETY

CHAPTER 4. COMMERCIAL VEHICLE REGULATIONS AND ENFORCEMENT PROCEDURES

SUBCHAPTER A. REGULATIONS GOVERNING HAZARDOUS MATERIALS

37 TAC §4.1

The Texas Department of Public Safety (the department) proposes amendments to §4.1, concerning Transportation of Hazardous Materials. The proposed amendments are necessary to harmonize updates to Title 49, Code of Federal Regulations with those laws adopted by Texas

Suzy Whittenton, Chief Financial Officer, has determined that for each year of the first five-year period this rule is in effect there will be no fiscal implications for state or local government, or local economies.

Ms. Whittenton has also determined that there will be no adverse economic effect on small businesses or micro-businesses required to comply with the section as proposed. There is no anticipated economic cost to individuals who are required to comply with the rule as proposed. There is no anticipated negative impact on local employment.

Ms. Whittenton has determined that for each year of the first five-year period the rule is in effect the public benefit anticipated as a result of enforcing the rule will be maximum efficiency of the Motor Carrier Safety Assistance Program.

The department has determined that this proposal is not a "major environmental rule" as defined by Texas Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule that 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.

The department has determined that Chapter 2007 of the Texas Government Code does not apply to this proposal. Accordingly, the department is not required to complete a takings impact assessment regarding this proposal.

The Texas Department of Public Safety, in accordance with the Administrative Procedures Act, Texas Government Code, §2001, et seq., and Texas Transportation Code, Chapter 644, will hold a public hearing on Tuesday, April 5, 2016, at 9:00 a.m., at the Texas Department of Public Safety, Texas Highway Patrol Division, Building G Annex, 5805 North Lamar, Austin, Texas. The purpose of this hearing is to receive comments from all interested persons regarding adoption of the proposed amendments to Administrative Rule §4.1 regarding Transportation of Hazardous Materials, proposed for adoption under the authority of Texas Transportation Code, Chapter 644, which provides that the director shall, after notice and a public hearing, adopt rules regulating the safe operation of commercial motor vehicles.

Persons interested in attending this hearing are encouraged to submit advance written notice of their intent to attend the hearing and to submit a written copy of their comments. Correspondence should be addressed to Major Chris Nordloh, Texas Highway Patrol Division, Texas Department of Public Safety, P.O. Box 4087, Austin, Texas 78773-0500.

Persons with special needs or disabilities who plan to attend this hearing and who may need auxiliary aids or services are requested to contact Major Chris Nordloh at (512) 424-2775 at least three working days prior to the hearing so that appropriate arrangements can be made.

Other comments on this proposal may be submitted to Major Chris Nordloh, Texas Highway Patrol Division, Texas Department of Public Safety, P.O. Box 4087, Austin, Texas 78773-0500, (512) 424-2775. Comments must be received no later than thirty (30) days from the date of publication of this proposal.

These amendments are proposed pursuant to Texas Transportation Code, §644.051, which authorizes the director to adopt rules regulating the safe transportation of hazardous materials and the safe operation of commercial motor vehicles; and authorizes the director to adopt all or part of the federal safety regulations, by reference.

Texas Transportation Code, §644.051 is affected by this proposal.

§4.1. Transportation of Hazardous Materials.

(a) The director of the Texas Department of Public Safety incorporates, by reference, the Federal Hazardous Materials Regulations, Title 49, Code of Federal Regulations, Parts 107 (Subpart G), 171 - 173, 177, 178, 179 (Subpart E), and 180, including all interpretations thereto, for commercial vehicles operated in intrastate, interstate, or foreign commerce, as amended through February 1, 2016 [July 1, 2015]. All other references in this section to the Code of Federal Regulations also refer to amendments and interpretations issued through February 1, 2016 [July 1, 2015].

(b) Explanations and Exceptions.

(1) Certain terms when used in the federal regulations as adopted in subsection (a) of this section will be defined as follows:

(A) the definition of motor carrier will be the same as that given in Texas Transportation Code, ~~[Section]~~ §643.001(6);

(B) hazardous material shipper means a consignor, consignee, or beneficial owner of a shipment of hazardous materials;

(C) interstate or foreign commerce will include all movements by commercial motor vehicle, both interstate and intrastate, over the streets and highways of this state;

(D) department means the Texas Department of Public Safety;

(E) FMCSA field administrator, as used in the federal motor carrier safety regulations, means the director of the Texas Department of Public Safety or the designee of the director for vehicles operating in intrastate commerce;

(F) farm vehicle means any vehicle or combination of vehicles controlled and/or operated by a farmer or rancher being used to transport agriculture products, farm machinery, and farm supplies to or from a farm or ranch; and

(G) private carrier means any person not included in the terms "common carrier by motor vehicle" or "contract carrier by motor vehicle" who transports by commercial motor vehicle property of which the person is the owner, lessee, or bailee, when such transportation is for the purpose of sale, lease, rent or bailment, or in furtherance of commerce.

(2) All references in Title 49, Code of Federal Regulations, Parts 107 (Subpart G), 171 - 173, 177, 178, 179 (Subpart E), and 180 made to other modes of transportation, other than by motor vehicles operated on streets and highways of this state, will be excluded and not adopted by this department.

(3) Regulations adopted by this department, including the federal motor carrier safety regulations, will apply to farm tank trailers used exclusively to transport anhydrous ammonia from the dealer to the farm. The usage of non-specification farm tank trailers by motor carriers to transport anhydrous ammonia must be in compliance with Title 49, Code of Federal Regulations, §173.315(m).

(4) The reporting of hazardous material incidents as required by Title 49, Code of Federal Regulations, §171.15 and §171.16 for shipments of hazardous materials by highway is adopted by the department.

(5) Regulations adopted by this department, including the federal motor carrier safety regulations, will apply to an intrastate motor carrier transporting a flammable liquid petroleum product in a cargo tank. The usage of non-specification cargo tanks by motor carriers for the intrastate transportation of flammable liquid petroleum products must be in compliance with Title 49, Code of Federal Regulations, §173.8.

(6) Regulations and exceptions adopted herein are applicable to all drivers and vehicles transporting hazardous materials in interstate, foreign, or intrastate commerce.

(7) Nothing in this section shall be construed to prohibit an employer from requiring and enforcing more stringent requirements relating to safety of operation and employee safety and health.

(8) Penalties assessed for violations of the regulations adopted herein will be based upon the provisions of Texas Transportation Code, Chapter 644, and §4.16 of this title (relating to Administrative Penalties, Payment, Collection and Settlement of Penalties).

(9) A peace officer certified, in accordance with §4.13 of this title (relating to Authority to Enforce, Training and Certificate Requirements), to enforce the Federal Hazardous Material Regulations, as adopted in this section, may declare a vehicle out-of-service using the North American Standard Hazardous Materials Out-of-Service [Out-of-service] Criteria as a guideline.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 25, 2016.

TRD-201600943

D. Phillip Adkins
General Counsel

Texas Department of Public Safety

Earliest possible date of adoption: April 10, 2016

For further information, please call: (512) 424-5848



TITLE 43. TRANSPORTATION

PART 1. TEXAS DEPARTMENT OF TRANSPORTATION

CHAPTER 1. MANAGEMENT

SUBCHAPTER E. PROCEDURES IN CONTESTED CASE

43 TAC §§1.29, 1.37, 1.38

The Texas Department of Transportation (department) proposes amendments to §1.29, Notice of Hearing, §1.37, Notification of Decision, and §1.38, Motions for Rehearing, all concerning procedures in contested cases.

EXPLANATION OF PROPOSED AMENDMENTS

S.B. No. 1267, 84th Regular Session, 2015, amended Government Code, Chapter 2001, the Administrative Procedure Act (APA) to, among other things, make its deadlines more closely align with the Texas Rules of Civil Procedure and expand notice requirements. The department's procedures for contested cases, located in Title 43, Part 1, Chapter 1, Subchapter E of the Texas Administrative Code must be amended to comply with the changes to the APA made by S.B. 1267. The amendments substitute references to the APA for the restatement of statutory requirements provided in the current rules.

Amendments to §1.29, Notice of Hearing, replace a detailed description of the required contents of a notice of hearing with the simpler provision that a notice of hearing will conform with the notice requirements of the APA, which are provided by Government Code, §2001.052, as amended by S.B. 1267.

Amendments to §1.37, Notification of Decision, replace the requirement that a notification of decision will be sent to each party by first class mail with the statement that a notification will be sent to each party in the manner required by the APA. S.B. 1267 amended Government Code, §2001.142 to expand the methods that may be used to send the required notice and to add a process for determining when the notice was received.

Amendments to §1.38, Motions for Rehearing, make several changes relating to rehearing requests. The amendments delete subsection (a) because it is inaccurate; Government Code, §2001.145 provides exceptions to the requirement that a motion for rehearing is a prerequisite to an appeal of a decision or order in a contested case. The amendments also replace the deadlines for filing a motion for rehearing and a reply to a motion

for rehearing with references to the APA. Those deadlines are found in Government Code, §2001.146 and were amended by S.B. 1267. Finally, the amendments replace the statement that a notice of a ruling on a motion for rehearing will be sent to each party by first class mail with a statement that a notice will be sent to each party in the manner required by the APA. S.B. 1267 amended Government Code, §2001.142 to expand the methods that may be used to send notice of the decision on a motion for rehearing.

FISCAL NOTE

Mr. Benjamin H. Asher, Interim Chief Financial Officer, has determined that for each of the first five years in which the amendments as proposed are in effect, there will be no fiscal implications for state or local governments as a result of enforcing or administering the amendments.

Mr. Jeff Graham, General Counsel, has certified that there will be no significant impact on local economies or overall employment as a result of enforcing or administering the amendments.

PUBLIC BENEFIT AND COST

Mr. Graham has also determined that for each year of the first five years in which the sections are in effect, the public benefit anticipated as a result of enforcing or administering the amendments will be expanded deadlines and notice requirements benefiting entities involved in contested cases with the department. There are no anticipated economic costs for persons required to comply with the sections as proposed. There will be no adverse economic effect on small businesses.

SUBMITTAL OF COMMENTS

Written comments on the proposed amendments to §§1.29, 1.37, and 1.38 may be submitted to Rule Comments, Office of General Counsel, Texas Department of Transportation, 125 East 11th Street, Austin, Texas 78701-2483 or to RuleComments@txdot.gov with the subject line "Contested Case Rules." The deadline for receipt of comments is 5:00 p.m. on April 11, 2016. In accordance with Transportation Code, §201.811(a)(5), a person who submits comments must disclose, in writing with the comments, whether the person does business with the department, may benefit monetarily from the proposed amendments, or is an employee of the department.

STATUTORY AUTHORITY

The amendments are proposed under Transportation Code, §201.101, which provides the Texas Transportation Commission (commission) with the authority to establish rules for the conduct of the work of the department, and more specifically, Government Code, §2001.004, which requires a state agency to "adopt rules of practice stating the nature and requirements of all available formal and informal procedures" under the APA.

CROSS REFERENCE TO STATUTE

Government Code, §2001.052, and Chapter 2001, Subchapter F.

§1.29. Notice of Hearing.

(a) Issuance. The department will issue notice of a hearing in accordance with the instructions of the judge and by certified or registered mail to each party's last known address as shown in the department's records.

(b) Content. The content of a notice of hearing will conform with the requirements of the APA. [A notice of hearing is sufficient if it includes:]

{(1) a statement of the time, place, and nature of the hearing;}

{(2) a statement of the legal authority and jurisdiction under which the hearing is to be held;}

{(3) reference to the particular sections of the statutes and rules involved; and}

{(4) a short, plain statement of the matters asserted or, alternatively, the ALJ may direct the department to include a copy of the petition with the notice.}

§1.37. *Notification of Decision.*

(a) The commission or the executive director, as specified by statute or department rule, will issue the decision in a contested case.

(b) After ~~the commission or executive director issues~~ the decision ~~is issued under subsection (a) of this section~~, the executive director will send a copy of the decision ~~[by first class mail]~~ to each party or the party's authorized representative ~~in the manner required by the APA~~ [and will keep an appropriate record of the mailing].

§1.38. *Motions for Rehearing.*

~~{(a) Prerequisite to appeal. A motion for rehearing is a prerequisite to appeal.}~~

~~(a) [(b)] Filing motion. A party must file a motion for rehearing with the executive director within the period provided by the APA for such a filing. In addition to information required by the APA, the [20 days after the date the party or party's authorized representative is notified of the decision. For purposes of this subsection, a party or attorney of record is presumed notified on the third day after the date that the decision or order is mailed by first-class mail. The] motion must contain:~~

- ~~(1) the name and representative capacity of the person filing the motion;~~
- ~~(2) the style and official docket number assigned by SOAH, and a department reference number, if applicable;~~
- ~~(3) the date of the decision or order; and~~
- ~~(4) a concise statement of each alleged error.~~

~~(b) [(c)] Reply to motion for rehearing. A reply to a motion for rehearing must be filed with the executive director within the period provided by the APA for such a reply. [30 days after the date the party or party's authorized representative is notified of the decision. For purposes of this subsection, a party or attorney of record is presumed notified on the third day after the date that the decision or order is mailed by first-class mail.]~~

~~(c) [(d)] Ruling on motion for rehearing. The commission or the executive director, as specified by statute or department rule, will rule on a motion for rehearing and issue the ruling in accordance with the APA.~~

~~(d) [(e)] Notice of ruling. After [the commission or executive director issues] a ruling is issued on a motion for rehearing, the executive director will send a copy of the ruling in the manner provided by the APA ~~[by first class mail]~~ to each party or the party's authorized representative ~~[and will keep an appropriate record of the mailing]~~.~~

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 25, 2016.

TRD-201600941

Joanne Wright

Deputy General Counsel

Texas Department of Transportation

Earliest possible date of adoption: April 10, 2016

For further information, please call: (512) 463-8630

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CHAPTER 15. FINANCING AND
CONSTRUCTION OF TRANSPORTATION
PROJECTS

SUBCHAPTER E. FEDERAL, STATE, AND
LOCAL PARTICIPATION

43 TAC §15.52

The Texas Department of Transportation (department) proposes amendments to §15.52, concerning Agreements.

EXPLANATION OF PROPOSED AMENDMENTS

Subchapter E of 43 TAC Chapter 15 describes federal, state, and local responsibilities for cost participation in highway improvement projects. These amendments make several changes to §15.52, Agreements.

Amendments to §15.52(3)(A)(i)(I) change one of the criteria allowed for an adjustment to a local government's fixed price amount obligation under a joint participation agreement between the department and a local government for a highway improvement project. The amendments change the phrase "site conditions change" to allow an adjustment if certain conditions encountered at the project site differ materially from those indicated in or expected under the contract for the project, as described by 23 C.F.R. §109. The term "differing site conditions" is used to be consistent with those federal regulations.

Amendments to §15.52(3)(A)(ii)(II), change the wording of a factor that the department will consider when determining the fixed price amount. Currently, the rule provides "the need for expeditious project completion" as one of those factors. The amendment changes that wording to "the need for accelerated project delivery" in order to be consistent with the terminology used in Federal Highway Administration programs.

Amendments to §15.52(3)(C)(ii)(III), change the wording of a factor that the executive director will consider in approving a request for periodic payments. Currently, the rule provides "the need for expeditious project completion" as one of those factors. The amendment changes that wording to "the need for accelerated project delivery." This change is consistent with the change made to §15.52(3)(A)(ii)(II).

Amendments to §15.52(5) change the phrase "significantly changed site conditions" to "significantly differing site conditions" to correspond to the changes made by the amendments to §15.52(3)(A)(i)(I) described above.

Amendments to §15.52(6)(A) correct the reference to the rule provision that allows an adjustment to a local government's fixed price obligation under a joint participation agreement.

Amendments to §15.52(6)(B)(ii) provide that, when the specified percentage method of payment is used, the local government, rather than the department, is responsible for any extra funds required to complete the project. Under §15.52(6)(B)(ii),

as amended in 2014, the department determines the final cost of a project after its completion. If the department finds that the amount received is insufficient to pay the local government's funding share, the rule provides that the department is to pay the balance. If the amount received exceeds the local government's funding share, the excess is returned to the local government. This change more appropriately allocates the risk of cost overruns to the party that has the ability to manage the cost of the project.

Amendments to §15.52(6)(C) provide that, when the periodic payment method is used, the local government, rather than the department, is responsible for any extra funds required to complete the project. This is similar to the change made to §15.52(B)(ii) to cover the insufficiency, and more appropriately allocates the risk of cost overruns to the party that has the ability to manage the cost of the project.

Amendments to §15.52(8)(D)(iii) change one of the factors that the department evaluates to determine whether to approve a local government's request to manage one or more elements of performance of a project from "need for expeditious project completion" to "the need for accelerated project delivery." This change is made to be consistent with the changes made in §15.52(3)(A)(ii)(II).

FISCAL NOTE

Benjamin H. Asher, Interim Chief Financial Officer, has determined that for each of the first five years in which the amendments as proposed are in effect, there will be no fiscal implications for state or local governments as a result of enforcing or administering the amendments.

Ms. Janice Mullenix, Director, Contracts and Purchasing, has certified that there will be no significant impact on local economies or overall employment as a result of enforcing or administering the amendments.

PUBLIC BENEFIT AND COST

Ms. Mullenix has also determined that for each year of the first five years in which the sections are in effect, the public benefit anticipated as a result of enforcing or administering the amendments will be a more precise estimation of total project cost, thereby improving the local government and department budgeting process. There are no anticipated economic costs for persons required to comply with the sections as proposed. There will be no adverse economic effect on small businesses.

SUBMITTAL OF COMMENTS

Written comments on the proposed amendments to §15.52 may be submitted to Rule Comments, Office of General Counsel, Texas Department of Transportation, 125 East 11th Street, Austin, Texas 78701-2483 or to RuleComments@txdot.gov with the subject line "Federal, State, and Local Participation Rules." The deadline for receipt of comments is 5:00 p.m. on April 11, 2016. In accordance with Transportation Code, §201.811(a)(5), a person who submits comments must disclose, in writing with the comments, whether the person does business with the department, may benefit monetarily from the proposed amendments, or is an employee of the department.

STATUTORY AUTHORITY

The amendments are proposed under Transportation Code, §201.101, which provides the Texas Transportation Commission with the authority to establish rules for the conduct of the work of the department.

CROSS REFERENCE TO STATUTE

Transportation Code, Chapter 221; Transportation Code, Chapter 222, Subchapter C; and Transportation Code, §224.033.

§15.52. Agreements.

This section describes the contents of the department's joint participation agreement with a local government for a highway improvement project and the responsibilities of the parties to such an agreement.

(1) Right of entry. If the local government is the owner of the project site, it shall permit the department or its authorized representative to occupy the site to perform all activities required to execute the work.

(2) Right of way and utility relocations and adjustments. The local government will provide all necessary right of way and utility relocations and adjustments, whether publicly or privately owned, in accordance with §15.55 of this subchapter (relating to Construction Cost Participation). Existing utilities will be relocated and adjusted by the local government with respect to location and type of installation in accordance with the requirements of the department under §21.21 of this title (relating to State Participation in Relocation, Adjustment, and/or Removal) and Chapter 21, Subchapter C of this title (relating to Utility Accommodation).

(3) Funding arrangement. The agreement will specify the funding arrangement agreed upon by the department and the local government. The funding arrangement shall include any adjustments required by §15.55 of this subchapter. The funding arrangement agreed upon by the department and the local government for drainage construction costs will be as specified under §15.54(e) of this subchapter (relating to Construction).

(A) Standard (fixed price). The fixed price amount will be based on the estimated cost of the work to be performed by the department on a project for which state or federal funds are received.

(i) A local government is responsible for the fixed price amount, which is not subject to adjustment unless:

(I) differing site conditions are encountered [change];

(II) work requested by the local government is ineligible for federal participation; or

(III) the adjustment is mutually agreed on by the department and the local government.

(ii) In determining the fixed price amount, the department will consider:

(I) requests by the local government to include work that is ineligible for federal or state participation;

(II) the need for accelerated project delivery [expeditious project completion];

(III) the type of work proposed and the ability to accurately estimate its cost; and

(IV) any other considerations relating to the benefit of the state, the traveling public, and the operations of the department.

(iii) The department may refuse to enter into an agreement with a local government that has not previously complied with the financial obligations under an agreement entered into under this subchapter.

(B) Specified percentage. If approved by the executive director, the local government is responsible for all, or a specified per-

centage, as shown in Figure: 43 TAC §15.55(c) of this subchapter, of the direct costs incurred by the department for preliminary engineering, construction engineering, construction, and right of way, as well as the direct cost for any work included in the project which is ineligible for federal or state participation. For federally funded non-construction programs, the local government is responsible for any required match and for any work included that is ineligible for federal or state participation. The department will accept in-kind contributions for matching funds or other funds only under agreements that do not include highway construction.

(C) Periodic.

(i) The executive director may approve a local government to make periodic payments of its funding share only if:

(I) the periodic payments sought are based on the estimated cost for the work for which the funds are received and the local government proposes a schedule to repay the entire amount; and

(II) the local government does not have a delinquent obligation to the department, as defined in §5.10 of this title (relating to Collection of Debts).

(ii) In approving a request for periodic payments, the executive director will consider:

(I) inability of the local government to pay its total funding share prior to the department's scheduled date for contract letting, based upon population level, bonded indebtedness, tax base, and tax rate;

(II) past payment performance;

(III) need for accelerated project delivery [expeditious project completion];

(IV) whether the project is located in a local government that consists of all or a portion of an economically disadvantaged county; and

(V) any other considerations relating to the benefit of the state, the public, and the operations of the department.

(D) Off-State Highway System Bridge Program. For projects funded in the Off-State Highway System Bridge Program, the local government is responsible for a fixed amount that is based on the specified percentage, as shown in Figure: 43 TAC §15.55(c) of this subchapter, of the estimated direct costs for preliminary engineering, construction engineering, and construction, and for the actual direct costs for right of way and eligible utilities. The estimated direct costs that will be used to establish the fixed amount under this subparagraph, are based on the department's estimate of the eligible work at the time the agreement is executed. The local government is responsible for the estimated direct cost of any project cost item or portion of a cost item that is not eligible for federal participation under the Highway Bridge Program, 23 U.S.C. §144 and Highway Bridge Replacement and Rehabilitation Program, 23 C.F.R. §650 Subpart D. The fixed amount under this subparagraph will be adjusted through the execution of an amendment to reflect additional costs resulting from changes made at the request of the local government, either during preliminary engineering or construction.

(4) Interest. The department will not pay interest on funds provided by the local government. Funds provided by the local government will be deposited into, and retained in, the state treasury.

(5) Amendments. In the case of significantly differing [changed] site conditions or other mutually agreed upon changes in the scope of work authorized in the agreement, the department, and the local government will amend the funding agreement, setting forth

the reason for the change and establishing the revised participation to be provided by the local government.

(6) Payment provision. The agreement will establish the conditions for payment by the local government, including, but not limited to, the method of payment and the time of payment.

(A) Standard (fixed price). If a fixed price funding arrangement is used, the fixed price amount is not subject to adjustment, except as provided for in paragraph (3)(A)(i) [~~(3)(B)~~] of this section.

(B) Specified percentage.

(i) Upon execution of the agreement or at a later date, unless periodic payments have been requested by the local government and approved by the executive director, the local government will pay, as a minimum, its funding share for the estimated cost for any right of way and preliminary engineering for the project. Unless periodic payments have been requested by the local government and approved by the executive director, the local government, before the department's scheduled date for contract letting, will remit to the department an amount equal to the remainder of the local government's funding share for the project.

(ii) After the project is completed the final cost will be determined by the department, based on its standard accounting procedures. If it is found that the amount received is insufficient to pay the local government's funding share, then the department will notify the local government of the amount of the difference and the local government shall promptly transmit that amount to the department [shall pay the balancee]. If it is found that the amount received is in excess of the local government's funding share, the excess funds paid by the local government shall be returned.

(C) Periodic. After a periodically paid project is completed, the final cost will be determined by the department based on its standard accounting procedures. If it is found that the amount received is insufficient to pay the local government's funding share, then the department will notify the local government of the amount of the difference and the local government shall promptly transmit that amount to the department [shall pay the balancee]. If it is found that the amount received is in excess of the local government's funding share, the excess funds paid by the local government shall be returned.

(D) Off-State Highway System Bridge Program. For projects funded in the Off-State Highway System Bridge Program, the department will determine the final cost after the project is completed, based on its standard accounting procedures. The department will notify the local government of any amount due for payment of costs related to changes made at the request of the local government. The local government shall promptly transmit the required amount to the department.

(E) Valuation of in-kind contributions. Before the department may enter an agreement under which goods, services, or real estate are accepted rather than financial consideration, the department will document a value for the in-kind contributions consistent with 49 C.F.R. §18.24.

(7) Termination. If the local government withdraws from the project after the agreement is executed, it shall be responsible for all direct and indirect project costs incurred by the department for the items of work in which the local government is participating.

(8) Responsibilities of the parties. The local government and the department shall identify in the agreement which party will prepare or provide construction plans, perform construction, advertise for bids, award a construction contract, and perform construction supervision. Activities assigned to the local government must comply with

subparagraph (A) of this paragraph and have the approvals required by subparagraph (B) of this paragraph.

(A) Local government performance and management of projects. For state highway improvement projects and other projects using state or federal funds, the agreement between the department and a local government may provide for the local government to:

(i) perform, using employees under the direct control of the local government, a highway improvement project on the state highway system;

(ii) outsource preliminary project engineering and design, bid opening, award of construction to a contractor, and construction management by the local government or a consultant hired by the local government of an improvement project for which reimbursement is requested;

(iii) contract for highway construction; or

(iv) perform other projects as authorized by law.

(B) Approval authority. Before a local government may perform an act described in subparagraph (A) of this paragraph, the executive director must authorize the local government to perform that act. The executive director may also approve the performance by employees of the local government of projects or activities appurtenant to a state highway, including drainage facilities, surveying, traffic counts, driveway construction, landscaping, guardrails, and other items incidental to the roadway itself, such as signing, pavement markings, signals, illumination, and traffic management systems.

(C) Conditions. A local government may perform an act described in subparagraph (A) of this paragraph only if:

(i) the local government commits in the agreement to comply with all federal, state, and department requirements, standards, and specifications, and agrees to forfeit any claim to federal and state reimbursement if they fail to comply;

(ii) the project is authorized by the commission in the current Unified Transportation Program or by a specific minute order;

(iii) a project on the state highway system performed or managed by a local government is operationally beneficial to the state;

(iv) a roadway construction project requested by the local government that is to be on the state highway system, for which local management is proposed, is funded with at least 50 percent of the funds coming from a non-federal and non-state source, unless a lesser percentage is approved by the executive director;

(v) the local government agrees to pay any cost overruns in addition to its local participation on an off-state highway system bridge program project for which local management is proposed; and

(vi) the department reviews and approves all plans, contract awards, and change orders.

(D) Approval. The department will not approve any project that includes the local government improving freeway main-

lanes on the state highway system, without express written approval of the executive director. In determining its approval or disapproval of local government's request to manage one or more elements of performance and management of a project, the department will evaluate the following criteria:

(i) previous experience of the local government in performing the type of work proposed;

(ii) the capability of the local government to perform the type of work proposed or to award and manage a contract for that work in a timely manner, consistent with federal, state, and department regulations, standards, and specifications;

(iii) the need for accelerated project delivery [~~expeditious project completion~~];

(iv) department resources available to perform or manage the highway improvement project in an efficient and timely manner;

(v) cost effectiveness of local performance of the work as compared to awarding the highway improvement project through the competitive bidding process; and

(vi) any other considerations relating to the benefit of the state, the traveling public, and the operations of the department.

(9) Acknowledgment. The local government must acknowledge in the agreement that while not an agent, servant, nor employee of the state, it is responsible for its own acts and deeds and for those of its agents or employees during the performance of the work authorized in the contract.

(10) Local regulations. If any existing, future or proposed local ordinance, commissioners court order, rule, policy, or other directive, including, but not limited to, outdoor advertising or storm water drainage facility requirements, that is more restrictive than state or federal regulations, or any other locally proposed change, including, but not limited to, plats or re-plats, results in any increased cost to the department for a highway improvement project, the local government must commit in the agreement to being responsible for all increased costs associated with the ordinance, order, policy, directive, or change, regardless of the funding arrangement specified in the agreement.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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For further information, please call: (512) 463-8630

