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.

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PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 291. PHARMACIES

SUBCHAPTER A. ALL CLASSES OF PHARMACIES

22 TAC §291.6

The Texas State Board of Pharmacy proposes amendments to §291.6, concerning Pharmacy License Fees. The proposed amendments, if adopted, will decrease pharmacist license fees based on expected expenses.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that for the first five-year period the amendments to §291.6 are in effect, there will be fiscal implications for state government as a result of enforcing or administering the amended rule as follows:

Revenue Decrease

FY2016 = $328,092

FY2017 = $357,000

FY2018 = $357,000

FY2019 = $357,000

FY2020 = $357,000

There are no anticipated fiscal implications for local government.

Ms. Dodson has determined that, for each year of the first five-year period the amendments to §291.6 will be in effect, the public benefit anticipated as a result of enforcing the rule will be assuring that the Texas State Board of Pharmacy is adequately funded to carry out its mission. The effect on large, small or micro-businesses (pharmacies) will be the same as the economic cost to

an individual, if the pharmacy chooses to pay the fee for the individual.

Economic cost to persons who are required to comply with the amended rule will be a decrease of $102 for an initial license and a decrease of $102 for the renewal of a license.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-8008. Comments must be received by 5:00 p.m., July 31, 2014.

The amendments are proposed under §§551.002, 554.006, and 554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 and 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act. The Board interprets §554.006 as authorizing the agency to establish fees to cover the agency's expected expenses.

The statutes affected by this amendment: Texas Pharmacy Act, Chapters 551 - 566 and 568 and 569, Texas Occupations Code.

§291.6. Pharmacy License Fees.

(a) Initial License Fee.

(1) Prior to October 1, 2015, the [~~The~~] fee for an initial license shall be $500 for the initial registration period and for processing the application and issuance of the pharmacy license as authorized by the Act §554.006. Effective October 1, 2015, the fee for an initial license shall be $401 for the initial registration period and for processing the application and issuance of the pharmacy license as authorized by the Act §554.006.

(2) In addition, the following fees shall be collected:

(A) $15 surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act §564.051;

(B) prior to October 1, 2015, $15 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and effective October 1, 2015, $12 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(C) $5 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, Occupations Code.

(b) (No change.)

(c) Renewal Fee.

(1) Prior to October 1, 2015, the [~~The~~] fee for biennial renewal of a pharmacy license shall be $500 for processing the application and issuance of the pharmacy license as authorized by the Act §554.006. Effective October 1, 2015, the fee for biennial renewal of a pharmacy license shall be $401 for processing the application and issuance of the pharmacy license as authorized by the Act §554.006.

(2) In addition, the following fees shall be collected:

(A) $15 surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act §564.051;

(B) prior to October 1, 2015, $15 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and effective October 1, 2015, $12 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(C) $2 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, Occupations Code.

(d) (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.

Filed with the Office of the Secretary of State on May 30, 2014.

TRD-201402550
Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: July 13, 2014
For further information, please call: (512) 305-8073

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SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

22 TAC §§291.31 - 291.34

The Texas State Board of Pharmacy proposes amendments to §291.31, concerning Definitions; §291.32, concerning Personnel; §291.33, concerning Operational Standards; and §291.34, concerning Records.

The proposed amendments to §291.31, if adopted, implement provisions of Senate Bill (SB) 406 passed by the 83rd Texas Legislature to update the reference to advance practice registered nurses and eliminate the reference to "carry out" an order. The proposed amendments to §291.32, if adopted, clarify that the requirements for dispensing a prescription are the same for a pharmacist and for an intern and eliminate references to sterile compounding that are no longer necessary. The proposed amendments to §291.33, if adopted, implement the provisions of SB 869 passed by the 83rd Texas Legislature to eliminate the requirement for the pharmacist to notify the prescriber of a substitution of dosage form. The proposed amendments to §291.34, if adopted, implement provisions of SB 406 passed by the 83rd Texas Legislature to update the reference to advance practice registered nurses.

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 rules. There will be no anticipated cost to individuals.

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 the appropriate reference to advance practice registered nurses; ensure pharmacists and pharmacy interns are responsible for the dispensing of prescriptions; eliminate the requirement for pharmacists to notify prescribers of a substitution of dosage form; and eliminate references to sterile compounding that are no longer necessary.

Written comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-8008. Comments must be received by 5:00 p.m., July 31, 2014.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566, 568 and 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 - 566, 568 and 569, Texas Occupations Code.

§291.31. Definitions.

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

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

(3) Advanced practice registered nurse--A registered nurse licensed [~~approved~~] by the Texas Board of Nursing to practice as an advanced practice registered nurse on the basis of completion of an advanced education program. The term includes nurse practitioner, nurse midwife, nurse anesthetist, and clinical nurse specialist. The term is synonymous with advanced nurse practitioner and advanced practice nurse.

(4) - (8) (No change.)

[~~(9) Carrying out or signing a prescription drug order--The completion of a prescription drug order presigned by the delegating physician, or the signing of a prescription by an advanced practice nurse or physician assistant after the person has been designated with the Texas Medical Board by the delegating physician as a person delegated to sign a prescription. As specified in §157.056, of the Occupations Code, the following information must be provided on each prescription:~~]

[~~(A) patient's name and address;~~]

[~~(B) the drug to be dispensed including the name, strength, and quantity of the drug;~~]

[~~(C) directions to the patient regarding the taking of the drug and the dosage;~~]

[~~(D) the intended use of the drug, if appropriate;~~]

[~~(E) the name, address, and telephone number of the physician;~~]

[~~(F) the name, address, telephone number, identification number, and if the prescription is for a controlled substance, the DEA number of the advanced practice nurse or physician assistant completing the prescription drug order;~~]

[~~(G) the date; and~~]

[~~(H) the number of refills permitted.~~]

(9) [~~(10)~~] Confidential record--Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication order.

(10) [~~(11)~~] Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1-4 of the Texas Controlled Substances Act, as amended, or a drug, immediate precursor, or other substance included in Schedules I, II, III, IV, or V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(11) [~~(12)~~] Dangerous drug--A drug or device that:

(A) is not included in Penalty Group 1, 2, 3, or 4, Chapter 481, Health and Safety Code, and is unsafe for self-medication; or

(B) bears or is required to bear the legend:

(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or

(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."

(12) [~~(13)~~] Data communication device--An electronic device that receives electronic information from one source and transmits or routes it to another (e.g., bridge, router, switch or gateway).

(13) [~~(14)~~] Deliver or delivery--The actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.

(14) [~~(15)~~] Designated agent--

(A) a licensed nurse, physician assistant, pharmacist, or other individual designated by a practitioner to communicate prescription drug orders to a pharmacist;

(B) a licensed nurse, physician assistant, or pharmacist employed in a health care facility to whom the practitioner communicates a prescription drug order;

(C) an advanced practice registered nurse or physician assistant authorized by a practitioner to carry out or sign a prescription drug order for dangerous drugs under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code); or

(D) a person who is a licensed vocational nurse or has an education equivalent to or greater than that required for a licensed vocational nurse designated by the practitioner to communicate prescriptions for an advanced practice registered nurse or physician assistant authorized by the practitioner to sign prescription drug orders under Chapter 157 of the Medical Practice Act (Subtitle B, Occupations Code).

(15) [~~(16)~~] Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(16) [~~(17)~~] Dispensing error--An action committed by a pharmacist or other pharmacy personnel that causes the patient or patient's agent to take possession of a dispensed prescription drug and an individual subsequently discovers that the patient has received an incorrect drug product, which includes incorrect strength, incorrect dosage form, and/or incorrect directions for use.

(17) [~~(18)~~] Dispensing pharmacist--The pharmacist responsible for the final check of the dispensed prescription before delivery to the patient.

(18) [~~(19)~~] Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(19) [~~(20)~~] Downtime--Period of time during which a data processing system is not operable.

(20) [~~(21)~~] Drug regimen review--An evaluation of prescription drug orders and patient medication records for:

(A) known allergies;

(B) rational therapy-contraindications;

(C) reasonable dose and route of administration;

(D) reasonable directions for use;

(E) duplication of therapy;

(F) drug-drug interactions;

(G) drug-food interactions;

(H) drug-disease interactions;

(I) adverse drug reactions; and

(J) proper utilization, including overutilization or underutilization.

(21) [~~(22)~~] Electronic prescription drug order--A prescription drug order that is generated on an electronic application and transmitted as an electronic data file.

(22) [~~(23)~~] Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(23) [~~(24)~~] Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or, if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(24) [~~(25)~~] Hard copy--A physical document that is readable without the use of a special device.

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

(26) [~~(27)~~] Medical Practice Act--The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

(27) [~~(28)~~] Medication order--A written order from a practitioner or a verbal order from a practitioner or his authorized agent for administration of a drug or device.

(28) [~~(29)~~] New prescription drug order--A prescription drug order that:

(A) has not been dispensed to the patient in the same strength and dosage form by this pharmacy within the last year;

(B) is transferred from another pharmacy; and/or

(C) is a discharge prescription drug order. (Note: furlough prescription drug orders are not considered new prescription drug orders.)

(29) [~~(30)~~] Original prescription--The:

(A) original written prescription drug order; or

(B) original verbal or electronic prescription drug order reduced to writing either manually or electronically by the pharmacist.

(30) [~~(31)~~] Part-time pharmacist--A pharmacist who works less than full-time.

(31) [~~(32)~~] Patient med-pak--A package prepared by a pharmacist for a specific patient comprised of a series of containers and containing two or more prescribed solid oral dosage forms. The patient med-pak is so designed or each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken.

(32) [~~(33)~~] Patient counseling--Communication by the pharmacist of information to the patient or patient's agent in order to improve therapy by ensuring proper use of drugs and devices.

(33) [~~(34)~~] Pharmaceutical care--The provision of drug therapy and other pharmaceutical services intended to assist in the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

(34) [~~(35)~~] Pharmacist-in-charge--The pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(35) [~~(36)~~] Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.

(36) [~~(37)~~] Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

(37) [~~(38)~~] Physician assistant--A physician assistant recognized by the Texas Medical Board as having the specialized education and training required under Subtitle B, Chapter 157, Occupations Code, and issued an identification number by the Texas Medical Board.

(38) [~~(39)~~] Practitioner--

(A) a person licensed or registered to prescribe, distribute, administer, or dispense a prescription drug or device in the course of professional practice in this state, including a physician, dentist, podiatrist, or veterinarian but excluding a person licensed under this Act;

(B) a person licensed by another state, Canada, or the United Mexican States in a health field in which, under the law of this state, a license holder in this state may legally prescribe a dangerous drug;

(C) a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration registration number and who may legally prescribe a Schedule II, III, IV, or V controlled substance, as specified under Chapter 481, Health and Safety Code, in that other state; or

(D) an advanced practice registered nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders under §§157.0511, 157.052, 157.053, 157.054, 157.0541, or 157.0542, Occupations Code, or, for the purpose of this subchapter, a pharmacist who practices in a hospital, hospital-based clinic, or an academic health care institution and a physician has delegated the authority to sign a prescription for a dangerous drug under §157.101, Occupations Code.

(39) [~~(40)~~] Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container into a prescription container for dispensing by a pharmacist to the ultimate consumer.

(40) [~~(41)~~] Prescription department--The area of a pharmacy that contains prescription drugs.

(41) [~~(42)~~] Prescription drug--

(A) a substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;

(B) a drug or device that under federal law is required, before being dispensed or delivered, to be labeled with the statement:

(i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or

(ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(C) a drug or device that is required by federal or state statute or regulation to be dispensed on prescription or that is restricted to use by a practitioner only.

(42) [~~(43)~~] Prescription drug order--

(A) a written order from a practitioner or a verbal order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) a written order or a verbal order pursuant to Subtitle B, Chapter 157, Occupations Code.

(43) [~~(44)~~] Prospective drug use review--A review of the patient's drug therapy and prescription drug order or medication order prior to dispensing or distributing the drug.

(44) [~~(45)~~] State--One of the 50 United States of America, a U.S. territory, or the District of Columbia.

(45) [~~(46)~~] Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.

(46) [~~(47)~~] Written protocol--A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas Medical Board under the Texas Medical Practice Act.

§291.32. Personnel.

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

(c) Pharmacists.

(1) General.

(A) - (E) (No change.)

(F) A dispensing pharmacist shall be responsible for and ensure that the drug is dispensed and delivered safely, and accurately as prescribed, unless the pharmacy's data processing system can record the identity of each pharmacist involved in a specific portion of the dispensing processing. If the system can track the identity of each pharmacist involved in the dispensing process, each pharmacist involved in the dispensing process shall be responsible for and ensure that the portion of the process the pharmacist is performing results in the safe and accurate dispensing and delivery of the drug as prescribed. The dispensing process shall include, but not be limited to, drug regimen review and verification of accurate prescription data entry, including data entry of prescriptions placed on hold, packaging, preparation, compounding, transferring, and labeling, and performance of the final check of the dispensed prescription. An intern has the same responsibilities described in this subparagraph as a pharmacist but must perform his or her duties under the supervision of a pharmacist.

(2) (No change.)

(3) Special requirements for compounding.

[~~(A)~~] [~~Non-Sterile Preparations.~~] All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

[~~(B) Sterile Preparations. All pharmacists engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).~~]

(d) Pharmacy Technicians and Pharmacy Technician Trainees.

(1) General.

(A) All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Special requirements for compounding.

[~~(i)~~] [~~Non-Sterile Preparations.~~] All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title.

[~~(ii) Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title.~~]

(2) Duties.

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

(C) Pharmacy technicians and pharmacy technician trainees may perform only nonjudgmental technical duties associated with the preparation and distribution of prescription drugs, as follows:

(i) initiating and receiving refill authorization requests;

(ii) entering prescription data into a data processing system;

(iii) taking a stock bottle from the shelf for a prescription;

(iv) preparing and packaging prescription drug orders (i.e., counting tablets/capsules, measuring liquids and placing them in the prescription container);

(v) affixing prescription labels and auxiliary labels to the prescription container;

(vi) reconstituting medications;

(vii) prepackaging and labeling prepackaged drugs;

(viii) loading bulk unlabeled drugs into an automated dispensing system provided a pharmacist verifies that the system is properly loaded prior to use;

(ix) compounding non-sterile [~~and sterile~~] prescription drug orders; and

(x) compounding bulk non-sterile preparations.

(3) (No change.)

(e) (No change.)

§291.33. Operational Standards.

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

(c) Prescription dispensing and delivery.

(1) - (3) (No change.)

(4) Substitution of dosage form.

(A) As specified in §562.012 [~~§562.002~~] of the Act, a pharmacist may dispense a dosage form of a drug product different from that prescribed, such as a tablet instead of a capsule or liquid instead of tablets, provided:

(i) the patient consents to the dosage form substitution; and

~~*[(ii)* the pharmacist notifies the practitioner of the dosage form substitution; and]~~

(ii) [~~(iii)~~] the dosage form so dispensed:

(I) contains the identical amount of the active ingredients as the dosage prescribed for the patient;

(II) is not an enteric-coated or time release product;

(III) does not alter desired clinical outcomes;

(B) Substitution of dosage form may not include the substitution of a product that has been compounded by the pharmacist unless the pharmacist contacts the practitioner prior to dispensing and obtains permission to dispense the compounded product.

(5) - (8) (No change.)

(d) - (i) (No change.)

§291.34. Records.

(a) (No change.)

(b) Prescriptions.

(1) (No change.)

(2) Written prescription drug orders.

(A) - (C) (No change.)

(D) Prescription drug orders carried out or signed by an advanced practice registered nurse, physician assistant, or pharmacist.

(i) A pharmacist may dispense a prescription drug order that is:

(I) [~~carried out or~~] signed by an advanced practice registered nurse or physician assistant provided the advanced practice registered nurse or physician assistant is practicing in accordance with Subtitle B, Chapter 157, Occupations Code;[~~,~~] and

(II) for a dangerous drug and signed by a pharmacist under delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations Code.

(ii) Each practitioner shall designate in writing the name of each advanced practice registered nurse or physician assistant authorized to [~~carry out or~~] sign a prescription drug order pursuant to Subtitle B, Chapter 157, Occupations Code. A list of the advanced practice registered nurses or physician assistants designated by the practitioner must be maintained in the practitioner's usual place of business. On request by a pharmacist, a practitioner shall furnish the pharmacist with a copy of the written authorization for a specific advanced practice registered nurse or physician assistant.

(E) (No change.)

(3) - (6) (No change.)

(7) Prescription drug order information.

(A) All original prescriptions shall bear:

(i) name of the patient, or if such drug is for an animal, the species of such animal and the name of the owner;

(ii) address of the patient, provided, however, a prescription for a dangerous drug is not required to bear the address of the patient if such address is readily retrievable on another appropriate, uniformly maintained pharmacy record, such as medication records;

(iii) name, address and telephone number of the practitioner at the practitioner's usual place of business, legibly printed or stamped and if for a controlled substance, the DEA registration number of the practitioner;

(iv) name and strength of the drug prescribed;

(v) quantity prescribed numerically and if for a controlled substance:

(I) numerically, followed by the number written as a word, if the prescription is written;

(II) numerically, if the prescription is electronic; or

(III) if the prescription is communicated orally or telephonically, as transcribed by the receiving pharmacist;

(vi) directions for use;

(vii) intended use for the drug unless the practitioner determines the furnishing of this information is not in the best interest of the patient;

(viii) date of issuance;

(ix) if a faxed prescription:

(I) a statement that indicates that the prescription has been faxed (e.g., Faxed to); and

(II) if transmitted by a designated agent, the name of the designated agent;

(x) if electronically transmitted:

(I) the date the prescription drug order was electronically transmitted to the pharmacy, if different from the date of issuance of the prescription; and

(II) if transmitted by a designated agent, the name of the designated agent; and

(xi) if issued by an advanced practice registered nurse or physician assistant in accordance with Subtitle B, Chapter 157, Occupations Code the:

(I) name, address, telephone number, and if the prescription is for a controlled substance, the DEA number of the supervising practitioner; and

(II) address and telephone number of the clinic where the prescription drug order was carried out or signed.

(B) (No change.)

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

(c) - (d) (No change.)

(e) Prescription drug order records maintained in a data processing system.

(1) (No change.)

(2) Records of dispensing.

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

(C) The data processing system shall have the capacity to produce a daily hard copy printout of all original prescriptions dispensed and refilled. This hard copy printout shall contain the following information:

(i) unique identification number of the prescription;

(ii) date of dispensing;

(iii) patient name;

(iv) prescribing practitioner's name; and the supervising physician's name if the prescription was issued by an advanced practice registered nurse, physician assistant or pharmacist;

(v) name and strength of the drug product actually dispensed; if generic name, the brand name or manufacturer of drug dispensed;

(vi) quantity dispensed;

(vii) initials or an identification code of the dispensing pharmacist;

(viii) initials or an identification code of the pharmacy technician or pharmacy technician trainee performing data entry of the prescription, if applicable;

(ix) if not immediately retrievable via computer display, the following shall also be included on the hard copy printout:

(I) patient's address;

(II) prescribing practitioner's address;

(III) practitioner's DEA registration number, if the prescription drug order is for a controlled substance;

(IV) quantity prescribed, if different from the quantity dispensed;

(V) date of issuance of the prescription drug order, if different from the date of dispensing; and

(VI) total number of refills dispensed to date for that prescription drug order; and

(x) any changes made to a record of dispensing.

(D) - (K) (No change.)

(3) (No change.)

(f) - (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.

Filed with the Office of the Secretary of State on May 30, 2014.

TRD-201402546
Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: July 13, 2014
For further information, please call: (512) 305-8073

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SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)

22 TAC §291.76

The Texas State Board of Pharmacy proposes amendments to §291.76, concerning Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center. The proposed amendments, if adopted, clarify the labeling requirements for medications provided by ASC pharmacies; remove references to sterile compounding that are no longer necessary; and add tramadol to the record keeping requirements to be consistent with other sections.

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. There will be no anticipated cost to individuals.

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 out-patient medications provided by the pharmacy are adequately labeled; ensure appropriate records for tramadol are maintained by the pharmacy; and eliminate references to sterile compounding that are no longer necessary.

Written comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-8008. Comments must be received by 5:00 p.m., July 31, 2014.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566, 568 and 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 - 566, 568 and 569, Texas Occupations Code.

§291.76. Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center.

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

(c) Personnel.

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

(3) Pharmacists.

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

(C) Special requirements for compounding non-sterile preparations.

[(i)] [~~Non-Sterile Preparations.~~] All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

[(ii) ~~Sterile Preparations. All pharmacists engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).~~]

(4) Pharmacy technicians and pharmacy technician trainees.

(A) (No change.)

(B) Duties. Duties may include, but need not be limited to, the following functions, under the direct supervision of a pharmacist:

(i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials, electronic signature to the appropriate quality control records prior to distribution;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in §291.131 of this title;

~~*[(iv)* compounding sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees:]~~

~~*[(I)* have completed the training specified in §291.133 of this title; and]~~

~~*[(II)* are supervised by a pharmacist who has completed the sterile preparations training specified in §291.133 of this title, conducts in-process and final checks, and affixes his or her name, initials, or electronic signature to the label or if batch prepared to the appropriate quality control records. (The name, initials, or electronic signature are not required on the label if it is maintained in a permanent record of the pharmacy.)]~~

(iv) [~~(v)~~] bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(v) [~~(vi)~~] distributing routine orders for stock supplies to patient care areas;

(vi) [~~(vii)~~] entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section;

(vii) [~~(viii)~~] maintaining inventories of drug supplies;

(viii) [~~(ix)~~] maintaining pharmacy records; and

(ix) [~~(x)~~] loading bulk unlabeled drugs into an automated drug dispensing system provided a pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his or her name, initials or electronic signature to the appropriate quality control records.

(C) Procedures.

(i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard written procedures and guidelines.

(ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as pharmacy technicians or pharmacy technician trainees working in a Class A pharmacy.

(D) Special requirements for compounding non-sterile preparations.

[(i)] [~~Non-Sterile Preparations.~~] All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title.

~~*[(ii)* Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title.]~~

(5) - (6) (No change.)

(d) Operational standards.

(1) Licensing requirements.

(A) - (J) (No change.)

~~[(K) Prior to August 31, 2014, an ASC pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133 of this title.]~~

(K) [~~(L)~~] Effective August 31, 2014, an ASC pharmacy shall not compound sterile preparations unless the pharmacy has applied for and obtained a Class C-S pharmacy.

(L) [~~(M)~~] An ASC pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

(M) [~~(N)~~] An ASC pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

(2) - (8) (No change.)

(9) Drugs supplied for postoperative use. Drugs supplied to patients for postoperative use shall be supplied according to the following procedures.

(A) - (C) (No change.)

(D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including name, address, phone number, and necessary auxiliary labels) by the pharmacy, provided, however that topicals and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-hour supply.

(E) - (H) (No change.)

(e) Records.

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

(3) Patient records.

(A) - (F) (No change.)

(G) Data processing system maintenance of records for the distribution and return of all controlled substances, nalbuphine (Nubain), or tramadol (Ultram) [~~carisoprodol (Soma)~~] to the pharmacy.

(i) Each time a controlled substance, nalbuphine (Nubain), or tramadol (Ultram) [~~carisoprodol (Soma)~~] is distributed from or returned to the pharmacy, a record of such distribution or return shall be entered into the data processing system.

(ii) The data processing system shall have the capacity to produce a hard-copy printout of an audit trail of drug distribution and return for any strength and dosage form of a drug (by either brand

or generic name or both) during a specified time period. This printout shall contain the following information:

(I) patient's name and room number or patient's facility identification number;

(II) prescribing or attending practitioner's name;

(III) name, strength, and dosage form of the drug product actually distributed;

(IV) total quantity distributed from and returned to the pharmacy;

(V) if not immediately retrievable via electronic image, the following shall also be included on the printout:

(-a-) prescribing or attending practitioner's address; and

(-b-) practitioner's DEA registration number, if the medication order is for a controlled substance.

(iii) An audit trail printout for each strength and dosage form of these drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the facility. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

(iv) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law enforcement or regulatory agencies.

(H) - (I) (No change.)

(4) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practitioner, another pharmacy, or other registrant, without being registered to distribute, under the following conditions.

(A) - (C) (No change.)

(D) If the distribution is for a Schedule [I ~~or~~] II controlled substance, the following is applicable.

(i) The pharmacy, practitioner, or other registrant who is receiving the controlled substances shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222C) to the distributing pharmacy.

(ii) The distributing pharmacy shall:

(I) complete the area on the DEA order form (DEA 222C) titled "To Be Filled in by Supplier";

(II) maintain Copy 1 of the DEA order form (DEA 222C) at the pharmacy for two years; and

(III) forward Copy 2 of the DEA order form (DEA 222C) to the divisional office of the Drug Enforcement Administration.

(5) - (6) (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) 305-8073

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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, clarify the training requirements for pharmacy technicians in American Society of Health-System Pharmacists accredited programs.

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. There is no anticipated cost to individuals.

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 adequate training for individuals involved in compounding of sterile preparations.

Written comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-8008. Comments must be received by 5:00 p.m., July 31, 2014.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566, 568 and 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 - 566, 568 and 569, Texas Occupations Code.

§291.133. Pharmacies Compounding Sterile Preparations.

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

(c) Personnel.

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

(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:

(-a-) the compounding occurs only during times the individual is assigned to a pharmacy as a part of the experiential component of the American Society of Health-System Pharmacists training program;

(-b-) the individual is under the direct supervision of and responsible to a pharmacist who has completed training as specified in paragraph (2) of this subsection; and

(-c-) the supervising pharmacist conducts in-process and final checks.

(ii) acquire the required experiential portion of the training programs specified in this subparagraph under the supervision of an individual who has already completed training as specified in paragraph (2) of this subsection or this paragraph.

(C) 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 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 [~~comply with the following~~]:

(I) have initial training obtained either through completion of:

(-a-) [~~(I)~~] [~~complete through completion of~~] 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-) [~~(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 [~~the areas~~]. 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-) [~~(III)~~] possess knowledge about:

(-1-) [~~(-a-)~~] aseptic processing;

(-2-) [~~(-b-)~~] quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;

(-3-) [~~(-c-)~~] chemical, pharmaceutical, and clinical properties of drugs;

(-4-) [~~(-d-)~~] container, equipment, and closure system selection; and

(-5-) [~~(-e-)~~] 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:

(I) the compounding occurs only during times the individual is assigned to a pharmacy as a part of the experiential component of the American Society of Health-System Pharmacists training program;

(II) the 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) the supervising pharmacist conducts in-process and final checks.

(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) - (5) (No change.)

(d) - (g) (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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SUBCHAPTER H. OTHER CLASSES OF PHARMACY

22 TAC §291.151

The Texas State Board of Pharmacy proposes amendments to §291.151, concerning Pharmacies Located in a Freestanding Emergency Medical Care Center (Class F). The proposed amendments, if adopted, clarify the labeling requirements for medications provided by Class F pharmacies; remove references to sterile compounding that are no longer necessary; and add tramadol to the record keeping requirements to be consistent with other sections.

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. There will be no anticipated cost to individuals.

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 outpatient medications provided by the pharmacy are adequately labeled; ensure appropriate records for tramadol are maintained by the pharmacy; and eliminate references to sterile compounding that are no longer necessary.

Written comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-8008. Comments must be received by 5:00 p.m., July 31, 2014.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566, 568 and 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 - 566, 568 and 569, Texas Occupations Code.

§291.151. Pharmacies Located in a Freestanding Emergency Medical Care Center (Class F).

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

(c) Personnel.

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

(3) Pharmacists.

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

(C) Special requirements for compounding non-sterile preparations.

[(i)] [~~Non-Sterile Preparations.~~] All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

[(ii) ~~Sterile Preparations. All pharmacists engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).~~]

(4) Pharmacy technicians and pharmacy technician trainees.

(A) (No change.)

(B) Duties. Duties may include, but need not be limited to, the following functions, under the direct supervision of a pharmacist:

(i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials, electronic signature to the appropriate quality control records prior to distribution;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in §291.131 of this title;

[(iv) ~~compounding sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees:~~]

[(I) ~~have completed the training specified in §291.133 of this title; and~~]

[(II) ~~are supervised by a pharmacist who has completed the sterile preparations training specified in §291.133 of this title, conducts in-process and final checks, and affixes his or her name, initials, or electronic signature to the label or if batch prepared to the appropriate quality control records. (The name, initials, or electronic signature are not required on the label if it is maintained in a permanent record of the pharmacy.)~~]

(iv) [~~(v)~~] bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(v) [~~(vi)~~] distributing routine orders for stock supplies to patient care areas;

(vi) [~~(vii)~~] entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section;

(vii) [~~(viii)~~] maintaining inventories of drug supplies;

(viii) [~~(ix)~~] maintaining pharmacy records; and

(ix) [~~(x)~~] loading bulk unlabeled drugs into an automated drug dispensing system provided a pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his or her name, initials or electronic signature to the appropriate quality control records.

(C) (No change.)

(D) Special requirements for compounding non-sterile preparations.

[(i)] [~~Non-Sterile Preparations.~~] All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title.

[(ii) ~~Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding sterile~~

~~preparations shall meet the training requirements specified in §291.133 of this title.]~~

(5) - (6) (No change.)

(d) Operational standards.

(1) Licensing requirements.

(A) - (I) (No change.)

~~[(J) A FEMCC pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133 of this title.]~~

(2) - (8) (No change.)

(9) Drugs supplied for outpatient use. Drugs supplied to patients for outpatient use shall be supplied according to the following procedures.

(A) - (C) (No change.)

(D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including name, address, phone number of the facility and necessary auxiliary labels) by the pharmacy, provided, however that topicals and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-hour supply.

(E) - (H) (No change.)

(e) Records.

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

(3) Patient records.

(A) - (F) (No change.)

(G) Data processing system maintenance of records for the distribution and return of all controlled substances, tramadol (Ultram), and nalbuphine (Nubain) to the pharmacy.

(i) Each time a controlled substance, tramadol (Ultram), or nalbuphine (Nubain) is distributed from or returned to the pharmacy, a record of such distribution or return shall be entered into the data processing system.

(ii) The data processing system shall have the capacity to produce a hard-copy printout of an audit trail of drug distribution and return for any strength and dosage form of a drug (by either brand or generic name or both) during a specified time period. This printout shall contain the following information:

(I) patient's name and room number or patient's facility identification number;

(II) prescribing or attending practitioner's name;

(III) name, strength, and dosage form of the drug product actually distributed;

(IV) total quantity distributed from and returned to the pharmacy;

(V) if not immediately retrievable via electronic image, the following shall also be included on the printout:

(-a-) prescribing or attending practitioner's address; and

(-b-) practitioner's DEA registration number, if the medication order is for a controlled substance.

(iii) An audit trail printout for each strength and dosage form of these drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the facility. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

(iv) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy, or other authorized local, state, or federal law enforcement or regulatory agencies.

(H) - (I) (No change.)

(4) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practitioner, another pharmacy, or other registrant, without being registered to distribute, under the following conditions.

(A) - (C) (No change.)

(D) If the distribution is for a Schedule [~~I or~~] II controlled substance, the following is applicable.

(i) The pharmacy, practitioner, or other registrant who is receiving the controlled substances shall issue Copy 1 and Copy 2 of a DEA order form (DEA 222C) to the distributing pharmacy.

(ii) The distributing pharmacy shall:

(I) complete the area on the DEA order form (DEA 222C) titled "To Be Filled in by Supplier";

(II) maintain Copy 1 of the DEA order form (DEA 222C) at the pharmacy for two years; and

(III) forward Copy 2 of the DEA order form (DEA 222C) to the divisional office of the Drug Enforcement Administration.

(5) - (6) (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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CHAPTER 295. PHARMACISTS

22 TAC §295.5

The Texas State Board of Pharmacy proposes amendments to §295.5, concerning Pharmacist License or Renewal Fees. The proposed amendments to §295.5, if adopted, will decrease pharmacist license fees based on expected expenses.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the amendments to §295.5 are in effect, there will be fiscal implications for state government as a result of enforcing or administering the amended rule as follows:

Revenue Decrease

FY2016 = $714,610

FY2017 = $851,000

FY2018 = $851,000

FY2019 = $851,000

FY2020 = $851,000

There are no anticipated fiscal implications for local government.

Ms. Dodson has determined that, for each year of the first five-year period the amendments to §295.5 will be in effect, the public benefit anticipated as a result of enforcing the rule will be assuring that the Texas State Board of Pharmacy is adequately funded to carry out its mission. The effect on large, small or micro-businesses (pharmacies) will be the same as the economic cost to an individual, if the pharmacy chooses to pay the fee for the individual.

Economic cost to persons who are required to comply with the amended rule will be a decrease of $46 for an initial license and a decrease of $46 for the renewal of a license.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-8008. Comments must be received by 5:00 p.m., July 31, 2014.

The amendments are proposed under §§551.002, 554.006, and 554.051 of the Texas Pharmacy Act (Chapters 551 - 566, 568 and 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act. The Board interprets §554.006 as authorizing the agency to establish fees to cover the agency's expected expenses.

The statutes affected by this amendment: Texas Pharmacy Act, Chapters 551 - 566, 568 and 569, Texas Occupations Code.

§295.5. Pharmacist License or Renewal Fees.

(a) Biennial Registration. The Texas State Board of Pharmacy shall require biennial renewal of all pharmacist licenses provided under the Pharmacy Act, §559.002.

(b) Initial License Fee.

(1) Prior to October 1, 2015, the [~~The~~] fee for the initial license shall be $281 for a two year registration and for processing the application and issuance of the pharmacist license as authorized by the Act, §554.006. Effective October 1, 2015, the fee for an initial license shall be $235 for a two year registration and for processing the application and issuance of the pharmacist license as authorized by the Act, §554.006.

(2) In addition, the following fees shall be collected:

(A) $13 surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act, §564.051;

(B) $5 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(C) $5 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, and Occupations Code.

(3) New pharmacist licenses shall be assigned an expiration date and initial fee shall be prorated based on the assigned expiration date.

(c) Renewal Fee.

(1) Prior to October 1, 2015, the [~~The~~] fee for biennial renewal of a pharmacist license shall be $281 for processing the application and issuance of the pharmacist license as authorized by the Act, §554.006. Effective October 1, 2015, the fee for biennial renewal of a pharmacist license shall be $235 for processing the application and issuance of the pharmacist license as authorized by the Act, §554.006.

(2) In addition, the following fees shall be collected:

(A) $13 surcharge to fund a program to aid impaired pharmacists and pharmacy students as authorized by the Act, §564.051;

(B) $5 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(C) $2 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, Occupations Code.

(d) - (e) (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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CHAPTER 297. PHARMACY TECHNICIANS AND PHARMACY TECHNICIAN TRAINEES

22 TAC §297.4

The Texas State Board of Pharmacy proposes amendments to §297.4, concerning Fees. The proposed amendments to §297.4, if adopted, will decrease pharmacy technician and pharmacy technician trainee fees based on expected expenses.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the amendments are in effect, there will be fiscal implications for state government as a result of enforcing or administering the amended rule as follows:

Revenue Decrease

FY2016 = $439,109

FY2017 = $479,000

FY2018 = $479,000

FY2019 = $479,000

FY2020 = $479,000

There are no anticipated fiscal implications for local government.

Ms. Dodson has determined that, for each year of the first five-year period the amendments to §297.4 will be in effect, the public benefit anticipated as a result of enforcing the rule will be assuring that the Texas State Board of Pharmacy is adequately funded

to carry out its mission. The effect on large, small or micro-businesses (pharmacies) will be the same as the economic cost to an individual, if the pharmacy chooses to pay the fee for the individual.

Economic cost to persons who are required to comply with the amended rule will be a decrease of $19 for an initial/renewal registration for pharmacy technicians and a decrease of $10 for an initial/renewal registration for pharmacy technician trainees.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-8008. Comments must be received by 5:00 p.m., July 31, 2014.

The amendments are proposed under §§551.002, 554.051, 568.005 of the Texas Pharmacy Act (Chapters 551 - 566, 568 and 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act. The Board interprets §568.005 as authorizing the agency to establish fees cover the agency's expected expenses.

The statutes affected by this amendment: Texas Pharmacy Act, Chapters 551 - 566, 568 and 569, Texas Occupations Code.

§297.4. Fees.

(a) Pharmacy technician trainee. Prior to October 1, 2015, the fee for registration shall be $55 for a two year registration for processing the application and issuance of the pharmacy technician trainee registration as authorized by the Act, §568.005. Effective October 1, 2015, the fee for registration shall be $45 for a two year registration for processing the application and issuance of the pharmacy technician trainee registration as authorized by the Act, §568.005. In addition, the following fees shall be collected: [~~The fee for registration shall be $62 and is composed of the following fees:~~]

[~~(1) $55 for processing the application and issuance of the pharmacy technician trainee registration as authorized by the Act, §568.005;~~]

(1) [~~(2)~~] $2 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(2) [~~(3)~~] $5 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, Occupations Code.

(b) Pharmacy technician.

(1) Biennial Registration. The board shall require biennial renewal of all pharmacy technician registrations provided under Chapter 568 of the Act.

(2) Initial Registration Fee. Prior to October 1, 2015, the fee for initial registration shall be $91 for a two year registration for processing the application and issuance of the pharmacy technician registration as authorized by the Act, §568.005. Effective October 1, 2015, the fee for registration shall be $72 for a two year registration for processing the application and issuance of the pharmacy technician registration as authorized by the Act, §568.005. In addition, the following fees shall be collected: [~~The fee for initial registration shall be $99 for a two year registration and is composed of the following fees:~~]

[~~(A) $91 for processing the application and issuance of the pharmacy technician registration as authorized by the Act, §568.005;~~]

(A) [~~(B)~~] $3 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(B) [~~(C)~~] $5 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, Occupations Code.

(3) Renewal Fee. Prior to October 1, 2015, the fee for biennial renewal shall be $91 for processing the application and issuance of the pharmacy technician registration as authorized by the Act, §568.005. Effective October 1, 2015, the fee for biennial renewal shall be $72 for processing the application and issuance of the pharmacy technician registration as authorized by the Act, §568.005. In addition, the following fees shall be collected: [~~The fee for biennial renewal of a pharmacy technician registration shall be $96 and is composed of the following:~~]

[~~(A) $91 for processing the application and issuance of the pharmacy technician registration as authorized by the Act, §568.005;~~]

(A) [~~(B)~~] $3 surcharge to fund TexasOnline as authorized by Chapter 2054, Subchapter I, Government Code; and

(B) [~~(C)~~] $2 surcharge to fund the Office of Patient Protection as authorized by Chapter 101, Subchapter G, Occupations Code.

(c) (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.

Filed with the Office of the Secretary of State on May 30, 2014.

TRD-201402545
Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
Earliest possible date of adoption: July 13, 2014
For further information, please call: (512) 305-8073

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