RULE ANALYSIS

Introduction: THE NEW RULE AND AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS A ADOPTED RULE

Short Title: Interchangeable Biological Products

Rule Numbers: §§ 309.1 – 309.8, 291.33, 291.34, 291.104

Statutory Authority: Texas Pharmacy Act, Chapter 551-569, Occupations Code:

(1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
(2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The new rule and amendments, if adopted, implement the provisions of HB 751 regarding interchangeable biological products.

The Board reviewed and voted to propose the amendments during the August 4, 2015, meeting. The proposed amendments were published in the September 25, 2015, issue of the Texas Register at 40 TexReg 6510, 6530, and 6545.
CHAPTER 309. SUBSTITUTION OF DRUG PRODUCTS

22 TAC §§309.1 - 309.8

The Texas State Board of Pharmacy proposes amendments to §309.1 concerning Objective, §309.2 concerning Definitions, §309.3 concerning Generic Substitution, §309.4 concerning Patient Notification, §309.6 concerning Records, §309.7 concerning Dispensing Responsibilities, and §309.8 concerning Advertising of Generic Drugs by Pharmacies and new §309.5 concerning Communication with Prescriber. The new rule and amendments, if adopted, implement the provisions of HB 751 regarding interchangeable biological products; and SB 460 regarding posting of the generic substitution sign.

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 and new rule will ensure pharmacists are substituting interchangeable biological products appropriately. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with these sections.

Comments on the amendments and new rule 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., October 30, 2015.

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

The statutes affected by these amendments and new rule: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§309.1 Objective.

These sections govern the substitution of lower-priced generically equivalent drug products for certain brand name drug products and the substitution of interchangeable biological products for certain biological products.

§309.2 Definitions.
The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act, §551.003 and Chapter 562.

1. **Act**—The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.
2. **Biological product**—A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.
3. **Biosimilar**—A biological product that is highly similar to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.
4. **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).
5. **Electronic prescription drug order**—A prescription drug order which is transmitted by an electronic device to the receiver (pharmacy).
6. **Generically equivalent**—A drug that is pharmaceutically equivalent and therapeutically equivalent to the drug prescribed.
7. **Interchangeable**—Referencing a biological product that is:
   - (A) biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient; and if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product; or
   - (B) designated as therapeutically equivalent to another product by the United States Food and Drug Administration in the most recent edition or supplement of the United States Food and Drug Administration's references.
8. **Pharmaceutically equivalent**—Drug products that have identical amounts of the same active chemical ingredients in the same dosage form and that meet the identical compendial or other applicable standards of strength, quality, and purity according to the United States Pharmacopoeia or another nationally recognized compendium.
(9) Reference product--A single biological product against which a biological product is evaluated and is found to be biosimilar.

(10) [66] Therapeutically equivalent--Pharmacologically equivalent drug products that, if administered in the same amounts, will provide the same therapeutic effect, identical in duration and intensity.

(11) [77] Original prescription--The:

(A) original written prescription drug orders; or

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

(12) [88] 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, therapeutic optometrist, or veterinarian but excluding a person licensed under this subtitle;

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

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

(D) An advanced practice registered nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders under §§157.0511, 157.0512, or [157.052, 157.053,] 157.054, [157.0541, or 157.0542,] Occupations Code.

§309.3. [Generic] Substitution Requirements.

(a) General requirements. In accordance with Chapter 562 of the Act, a pharmacist may dispense a generically equivalent drug or interchangeable biological product if:

(1) the generic drug or interchangeable biological product costs the patient less than the prescribed drug product;

(2) the patient does not refuse the substitution; and
(3) the practitioner does not certify on the prescription form that a specific prescribed brand is medically necessary as specified in a dispensing directive described in subsection (c) of this section.

(b) Prescription format for written prescription drug orders.

(1) A written prescription drug order issued in Texas may:

(A) be on a form containing a single signature line for the practitioner; and

(B) contain the following reminder statement on the face of the prescription: "A generically equivalent drug product may be dispensed unless the practitioner hand writes the words 'Brand Necessary' or 'Brand Medically Necessary' on the face of the prescription."

(2) A pharmacist may dispense a prescription that is not issued on the form specified in paragraph (1) of this subsection, however, the pharmacist may dispense a generically equivalent drug or interchangeable biological product unless the practitioner has prohibited substitution through a dispensing directive in compliance with subsection (c)(1) of this section.

(3) The prescription format specified in paragraph (1) of this subsection does not apply to the following types of prescription drug orders:

(A) prescription drug orders issued by a practitioner in a state other than Texas;

(B) prescriptions for dangerous drugs issued by a practitioner in the United Mexican States or the Dominion of Canada; or

(C) prescription drug orders issued by practitioners practicing in a federal facility provided they are acting in the scope of their employment.

(4) In the event of multiple prescription orders appearing on one prescription form, the practitioner shall clearly identify to which prescription(s) the dispensing directive(s) apply. If the practitioner does not clearly indicate to which prescription(s) the dispensing directive(s) apply, the pharmacist may substitute on all prescriptions on the form.

(c) Dispensing directive.

(1) General requirements. The following is applicable to the dispensing directive outlined in this subsection.

(A) When a prescription is issued for a brand name product that has no generic equivalent product, the pharmacist must dispense the brand name product. If a generic equivalent or interchangeable biological product becomes available, a pharmacist may substitute the generically equivalent or interchangeable biological product unless the practitioner has specified on the initial prescription that the brand name product is medically necessary.
(B) If the practitioner has prohibited substitution through a dispensing directive in compliance with this subsection, a pharmacist shall not substitute a generically equivalent drug or interchangeable biological product unless the pharmacist obtains verbal or written authorization from the practitioner, notes such authorization on the original prescription drug order, and notifies the patient in accordance with §309.4 of this title (relating to Patient Notification).

(2) Written prescriptions.

(A) A practitioner may prohibit the substitution of a generically equivalent drug or interchangeable biological product for a brand name drug product by writing across the face of the written prescription, in the practitioner's own handwriting, the phrase "brand necessary" or "brand medically necessary."

(B) The dispensing directive shall:

(i) be in a format that protects confidentiality as required by the Health Insurance Portability and Accountability Act of 1996 (29 U.S.C. Section 1181 et seq.) and its subsequent amendments; and

(ii) comply with federal and state law, including rules, with regard to formatting and security requirements.

(C) The dispensing directive specified in this paragraph may not be preprinted, rubber stamped, or otherwise reproduced on the prescription form.

(D) A practitioner may prohibit substitution on a written prescription only by following the dispensing directive specified in this paragraph. Two-line prescription forms, check boxes, or other notations on an original prescription drug order which indicate "substitution instructions" are not valid methods to prohibit substitution, and a pharmacist may substitute on these types of written prescriptions.

(3) Verbal Prescriptions.

(A) If a prescription drug order is transmitted to a pharmacist orally, the practitioner or practitioner's agent shall prohibit substitution by specifying "brand necessary" or "brand medically necessary." The pharmacist shall note any substitution instructions by the practitioner or practitioner's agent, on the file copy of the prescription drug order. Such file copy may follow the one-line format indicated in subsection (b)(1) of this section, or any other format that clearly indicates the substitution instructions.

(B) If the practitioner's or practitioner's agent does not clearly indicate that the brand name is medically necessary, the pharmacist may substitute a generically equivalent drug or interchangeable biological product.

(C) To prohibit substitution on a verbal prescription reimbursed through the medical assistance program specified in 42 C.F.R., §447.331:
(i) the practitioner or the practitioner's agent shall verbally indicate that the brand is medically necessary; and

(ii) the practitioner shall mail or fax a written prescription to the pharmacy which complies with the dispensing directive for written prescriptions specified in paragraph (1) of this subsection within 30 days.

(4) Electronic prescription drug orders.

(A) To prohibit substitution, the practitioner or practitioner's agent shall clearly indicate substitution instructions in the electronic prescription drug order.

(B) If the practitioner or practitioner's agent does not indicate or does not clearly indicate in the electronic prescription drug order that the brand is necessary, the pharmacist may substitute a generically equivalent drug or interchangeable biological product.

(C) To prohibit substitution on an electronic prescription drug order reimbursed through the medical assistance program specified in 42 C.F.R., §447.331, the practitioner shall comply with state and federal laws.

(5) Prescriptions issued by out-of-state, Mexican, Canadian, or federal facility practitioners.

(A) The dispensing directive specified in this subsection does not apply to the following types of prescription drug orders:

(i) prescription drug orders issued by a practitioner in a state other than Texas;

(ii) prescriptions for dangerous drugs issued by a practitioner in the United Mexican States or the Dominion of Canada; or

(iii) prescription drug orders issued by practitioners practicing in a federal facility provided they are acting in the scope of their employment.

(B) A pharmacist may not substitute on prescription drug orders identified in subparagraph (A) of this paragraph unless the practitioner has authorized substitution on the prescription drug order. If the practitioner has not authorized substitution on the written prescription drug order, a pharmacist shall not substitute a generically equivalent drug product unless:

(i) the pharmacist obtains verbal or written authorization from the practitioner (such authorization shall be noted on the original prescription drug order); or

(ii) the pharmacist obtains written documentation regarding substitution requirements from the State Board of Pharmacy in the state, other than Texas, in which the prescription drug order was issued. The following is applicable concerning this documentation.
The documentation shall state that a pharmacist may substitute on a prescription drug order issued in such other state unless the practitioner prohibits substitution on the original prescription drug order.

The pharmacist shall note on the original prescription drug order the fact that documentation from such other state board of pharmacy is on file.

Such documentation shall be updated yearly.

(d) Refills.

(1) Original substitution instructions. All refills shall follow the original substitution instructions unless otherwise indicated by the practitioner or practitioner's agent.

(2) Narrow therapeutic index drugs.

(A) The board and the Texas Medical Board shall establish a joint committee to recommend to the board a list of narrow therapeutic index drugs and the rules, if any, by which this paragraph applies to those drugs. The committee must consist of an equal number of members from each board. The committee members shall select a member of the committee to serve as presiding officer for a one year term. The presiding officer may not represent the same board as the presiding officer's predecessor.

(B) The board, on the recommendation of the joint committee, has determined that no drugs shall be included on a list of narrow therapeutic index drugs as defined in §562.014, Occupations Code.

(i) The board has specified in §309.7 of this title (relating to dispensing responsibilities) that for drugs listed in the publication, pharmacist shall use as a basis for determining generic equivalency, Approved Drug Products with Therapeutic Equivalence Evaluations and current supplements published by the Federal Food and Drug Administration, within the limitations stipulated in that publication. For drugs listed in the publications, pharmacists may only substitute products that are rated therapeutically equivalent in the Approved Drug Products with Therapeutic Equivalence Evaluations and current supplements.

(ii) Practitioners may prohibit substitution through a dispensing directive in compliance with subsection (c) of this section.

(C) The board shall reconsider the contents of the list if:

(i) the Federal Food and Drug Administration determines a new equivalence classification which indicates that certain drug products are equivalent but special notification to the patient and practitioner is required when substituting these products; or
(ii) any interested person petitions the board to reconsider the list. If the board receives a petition to include a drug on the list, the joint committee specified in subparagraph (A) of this paragraph shall review the request and make a recommendation to the board.

§309.4. Patient Notification.

(a) Substitution notification. Before delivery of a prescription for a generically equivalent drug or interchangeable biological product as authorized by Chapter 562, Subchapter A of the Act, a pharmacist must:

(1) personally, or through his or her agent or employee inform the patient or the patient's agent that a less expensive generically equivalent drug interchangeable biological product is available for the brand prescribed; and ask the patient or the patient's agent to choose between the generically equivalent drug or biological product and the brand prescribed.

(2) cause to be displayed, in a prominent place that is in clear public view where prescription drugs are dispensed, a sign in block letters not less than one inch in height that reads, in both English and Spanish: "TEXAS LAW REQUIRES A PHARMACIST TO INFORM YOU IF A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG IS AVAILABLE FOR CERTAIN BRAND NAME DRUGS AND TO ASK YOU TO CHOOSE BETWEEN THE GENERIC AND THE BRAND NAME DRUG. YOU HAVE A RIGHT TO ACCEPT OR REFUSE THE GENERICALLY EQUIVALENT DRUG."

(b) Exceptions. A pharmacy is not required to comply with the provisions of subsection (a) of this section:

(1) in the case of the refill of a prescription for which the pharmacy previously complied with subsection (a) of this section with regard to the same patient or patient's agent; or

(2) if the patient's physician or physician's agent advises the pharmacy that:

(A) the physician has informed the patient or the patient's agent that a less expensive generically equivalent drug or interchangeable biological product is available for the brand prescribed; and

(B) the patient or the patient's agent has chosen either the brand prescribed or the less expensive generically equivalent drug or interchangeable biological product.

(c) Notification by pharmacies delivering prescriptions by mail.
(1) A pharmacy that supplies a prescription by mail is considered to have complied with the provision of subsection (a) of this section if the pharmacy includes on the prescription order form completed by the patient or the patient's agent language that clearly and conspicuously:

(A) states that if a less expensive generically equivalent drug or interchangeable biological product is available for the brand prescribed, the patient or the patient's agent may choose between the generically equivalent drug or interchangeable biological product and the brand prescribed; and

(B) allows the patient or the patient's agent to indicate the choice of the generically equivalent drug or interchangeable biological product or the brand prescribed.

(2) If the patient or patient's agent fails to indicate otherwise to a pharmacy on the prescription order form under paragraph (1) of this subsection, the pharmacy may dispense a generically equivalent drug or interchangeable biological product.

(d) Inpatient notification exemption. Institutional pharmacies shall be exempt from the labeling provisions and patient notification requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication orders.

§309.5. Communication with Prescriber.

(a) Not later than the third business day after the date of dispensing a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer or national drug code number.

(b) The communication must be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy benefit management system or a pharmacy record, which may include information submitted for the payment of claims, that a pharmacist reasonably concludes is electronically accessible by the prescribing practitioner. Otherwise, the pharmacist or the pharmacist's designee shall communicate the biological product dispensed to the prescribing practitioner, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication is not required if:

(1) there is no interchangeable biological product approved by the United States Food and Drug Administration for the product prescribed; or

(2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(c) This section expires September 1, 2019.

§309.6. Records.
(a) When the pharmacist dispenses a generically equivalent drug or interchangeable biological product pursuant to the Subchapter A, Chapter 562 of the Act, the following information shall be noted on the original written or hard-copy of the oral prescription drug order:

1. any substitution instructions communicated orally to the pharmacist by the practitioner or practitioner's agent or a notation that no substitution instructions were given; and

2. the name and strength of the actual drug product dispensed shall be noted on the original or hard-copy prescription drug order. The name shall be either:

(A) the brand name and strength; or

(B) the generic name or the name of the interchangeable biological product, strength, and name of the manufacturer or distributor of such generic drug or interchangeable biological product. (The name of the manufacturer or distributor may be reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient to identify the manufacturer or distributor. For combination drug products having no brand name, the principal active ingredients shall be indicated on the prescription.)

(b) If a pharmacist refills a prescription drug order with a generically equivalent product or interchangeable biological product from a different manufacturer or distributor than previously dispensed, the pharmacist shall record on the prescription drug order the information required in subsection (a) of this section for the product dispensed on the refill.

(c) If a pharmacy utilizes patient medication records for recording prescription information, the information required in subsections (a) and (b) of this section shall be recorded on the patient medication records.

(d) The National Drug Code (NDC) of a drug or any other code may be indicated on the prescription drug order at the discretion of the pharmacist, but such code shall not be used in place of the requirements of subsections (a) and (b) of this section.

§309.7 Dispensing Responsibilities.

(a) The determination of the drug product to be substituted as authorized by the Subchapter A, Chapter 562 of the Act, is the professional responsibility of the pharmacist, and the pharmacist may not dispense any product that does not meet the requirements of the Subchapter A, Chapter 562 of the Act. [As specified in Chapter 562 of the Act and §309.2 of this title (relating to definitions), a generically equivalent product is one that is pharmaceutically equivalent and therapeutically equivalent to the drug prescribed.]

(b) Pharmacists shall use as a basis for the determination of generic equivalency or interchangeability as defined in the Subchapter A, Chapter 562 of the Act, most recent edition or supplement of the United States Food and Drug Administration's references (e.g., the Orange Book or Purple Book). [the following:]
(c) Pharmacists.

(1) For drugs listed in the publication, pharmacists shall use Approved Drug Products With Therapeutic Equivalence Evaluations (Orange Book) and current supplements published by the Federal Food and Drug Administration, within the limitations stipulated in that publication, to determine generic equivalency. Pharmacists may only substitute products that are rated therapeutically equivalent in the Orange Book and have an "A" rating. "A" rated drug products include but are not limited to, those designated AA, AB, AN, AO, AP, or AT in the Orange Book.

(2) For drugs not listed in the Orange Book, pharmacists shall use their professional judgment to determine generic equivalency.

(d) Pharmacists shall use Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book) and current supplements published by the Federal Food and Drug Administration, within the limitations stipulated in that publication, to determine biosimilarity to or interchangeability with a reference biological product.

§309.8 Advertising of Generic Drugs by Pharmacies.

Prescription drug advertising comparing generic drugs or biological products and brand name drugs or biological products is subject to the §554.054 of the Act and in compliance with federal law.

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 September 14, 2015.

TRD-201503760

Gay Dodson, R.Ph.

Executive Director

Texas State Board of Pharmacy

Earliest possible date of adoption: October 25, 2015

For further information, please call: (512) 305-8028
SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

22 TAC §§291.32 - 291.34

The Texas State Board of Pharmacy proposes amendments to §291.32 concerning Personnel, §291.33 concerning Operational Standards, and §291.34 concerning Records. The amendments, if adopted, clarify that pharmacists may not serve as the pharmacist-in-charge of other pharmacies if the pharmacist is required to be a full time pharmacist; correct grammar; clarify the duties of a pharmacist to include transferring or receiving a transfer of original prescription information on behalf of a patient; clarify that prescriptions must be transferred within four business hours; update the requirements with regard to interchangeable biological products; and update the rules regarding distributions to include dangerous drugs.

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 the pharmacies are adequately supervised by the pharmacist-in-charge; ensure only pharmacists are performing duties of a pharmacist; ensure patients receive transferred prescriptions in a timely manner; and ensure biologicals are handled appropriately. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with these sections.

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., October 30, 2015.

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

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

§291.32. Personnel.

(a) Pharmacist-in-charge.

(1) General.
(A) Each Class A pharmacy shall have one pharmacist-in-charge who is employed on a full-time basis, who may be the pharmacist-in-charge for only one such pharmacy; provided, however, such pharmacist-in-charge may be the pharmacist-in-charge of:

(i) more than one Class A pharmacy, if the additional Class A pharmacies are not open to provide pharmacy services simultaneously; or

(ii) during an emergency, up to two Class A pharmacies open simultaneously if the pharmacist-in-charge works at least 10 hours per week in each pharmacy for no more than a period of 30 consecutive days.

(B) The pharmacist-in-charge shall comply with the provisions of §291.17 of this title (relating to Inventory Requirements).

(C) The pharmacist-in-charge of a Class A pharmacy may not serve as the pharmacist-in-charge of a Class B pharmacy or a Class C pharmacy with 101 beds or more.

(2) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-charge may advise the owner on administrative or operational concerns. The pharmacist-in-charge shall have responsibility for, at a minimum, the following:

(A) educating and training of pharmacy technicians and pharmacy technician trainees;

(B) supervising a system to assure appropriate procurement of prescription drugs and devices and other products dispensed from the Class A pharmacy;

(C) disposing of and distributing drugs from the Class A pharmacy;

(D) storing all materials, including drugs, chemicals, and biologicals;

(E) maintaining records of all transactions of the Class A pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials required by applicable state and federal laws and sections;

(F) supervising a system to assure maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs;

(G) adhering to policies and procedures regarding the maintenance of records in a data processing system such that the data processing system is in compliance with Class A (community) pharmacy requirements;

(H) legally operating the pharmacy, including meeting all inspection and other requirements of all state and federal laws or sections governing the practice of pharmacy; and
(I) if the pharmacy uses an automated pharmacy dispensing system, shall be responsible for the following:

(i) consulting with the owner concerning and adherence to the policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(ii) inspecting medications in the automated pharmacy dispensing system, at least monthly, for expiration date, misbranding, physical integrity, security, and accountability;

(iii) assigning, discontinuing, or changing personnel access to the automated pharmacy dispensing system;

(iv) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed healthcare professionals performing any services in connection with an automated pharmacy dispensing system have been properly trained on the use of the system and can demonstrate comprehensive knowledge of the written policies and procedures for operation of the system; and

(v) ensuring that the automated pharmacy dispensing system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

(b) Owner. The owner of a Class A pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(1) establishing policies for procurement of prescription drugs and devices and other products dispensed from the Class A pharmacy;

(2) establishing policies and procedures for the security of the prescription department including the maintenance of effective controls against the theft or diversion of prescription drugs;

(3) if the pharmacy uses an automated pharmacy dispensing system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(4) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(5) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.
(c) Pharmacists.

(1) General.

(A) The pharmacist-in-charge shall be assisted by sufficient number of additional licensed pharmacists as may be required to operate the Class A pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

(B) All pharmacists shall assist the pharmacist-in-charge in meeting his or her responsibilities in ordering, dispensing, and accounting for prescription drugs.

(C) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for designating and delegating duties, other than those listed in paragraph (2) of this subsection, to pharmacy technicians and pharmacy technician trainees. Each pharmacist shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

(D) Pharmacists shall directly supervise pharmacy technicians and pharmacy technician trainees who are entering prescription data into the pharmacy's data processing system by one of the following methods.

(i) Physically present supervision. A pharmacist shall be physically present to directly supervise a pharmacy technician or pharmacy technician trainee who is entering prescription data into the data processing system. Each prescription entered into the data processing system shall be verified at the time of data entry. If the pharmacist is not physically present due to a temporary absence as specified in §291.33(b)(3) of this title (relating to Operational Standards), on return the pharmacist must:

(1) conduct a drug regimen review for the prescriptions data entered during this time period as specified in §291.33(c)(2) of this title; and

(2) verify that prescription data entered during this time period was entered accurately.

(ii) Electronic supervision. A pharmacist may electronically supervise a pharmacy technician or pharmacy technician trainee who is entering prescription data into the data processing system provided the pharmacist:

(I) is on-site, in the pharmacy where the technician/trainee is located;

(II) has immediate access to any original document containing prescription information or other information related to the dispensing of the prescription. Such access may be through imaging technology provided the pharmacist has the ability to review the original, hardcopy documents if needed for clarification; and

(III) verifies the accuracy of the data entered information prior to the release of the information to the system for storage and/or generation of the prescription label.
Electronic verification of data entry by pharmacy technicians or pharmacy technician trainees. A pharmacist may electronically verify the data entry of prescription information into a data processing system provided:

(I) a pharmacist is on-site in the pharmacy where the pharmacy technicians/trainees are located;

(II) the pharmacist electronically conducting the verification is either a:

(-a-) Texas licensed pharmacist; or

(-b-) pharmacist employed by a Class E pharmacy that:

(-1-) has the same owner as the Class A pharmacy where the pharmacy technicians/trainees are located; or

(-2-) has entered into a written contract or agreement with the Class A pharmacy, which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations;

(III) the pharmacy establishes controls to protect the privacy and security of confidential records; and

(IV) the pharmacy keeps permanent records of prescriptions electronically verified for a period of two years.

All pharmacists, while on duty, shall be responsible for the legal operation of the pharmacy and for complying with all state and federal laws or rules governing the practice of pharmacy.

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.

Duties. Duties which may only be performed by a pharmacist are as follows:

(A) receiving oral prescription drug orders and reducing these orders to writing, either manually or electronically;
(B) interpreting prescription drug orders;

(C) selecting drug products;

(D) performing the final check of the dispensed prescription before delivery to the patient to ensure that the prescription has been dispensed accurately as prescribed;

(E) communicating to the patient or patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment, the pharmacist deems significant, as specified in §291.33(c) of this title;

(F) communicating to the patient or the patient's agent on his or her request information concerning any prescription drugs dispensed to the patient by the pharmacy;

(G) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(H) interpreting patient medication records and performing drug regimen reviews;

(I) performing a specific act of drug therapy management for a patient delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with the Medical Practice Act; [and]

(J) verifying that controlled substances listed on invoices are received by clearly recording his/her initials and date of receipt of the controlled substances; [and][-]

(K) transferring or receiving a transfer of original prescription information on behalf of a patient.

(d) - (e) (No change.)

§291.33. Operational Standards.

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

(c) Prescription dispensing and delivery.

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

(3) [Generic] Substitution of generically equivalent drugs or interchangeable biological products. A pharmacist may dispense a generically equivalent drug or interchangeable biological product and shall comply with the provisions of §309.3 of this title (relating to [Generic] Substitution Requirements).

(4) - (6) (No change.)

(7) Labeling.
At the time of delivery of the drug, the dispensing container shall bear a label in plain language and printed in an easily readable font size, unless otherwise specified, with at least the following information:

(i) name, address and phone number of the pharmacy;

(ii) unique identification number of the prescription that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman;

(iii) date the prescription is dispensed;

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

(v) name of the prescribing practitioner;

(vi) if the prescription was signed by a pharmacist, the name of the pharmacist who signed the prescription for a dangerous drug under delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations Code;

(vii) name of the patient or if such drug was prescribed for an animal, the species of the animal and the name of the owner that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman. The name of the patient's partner or family member is not required to be on the label of a drug prescribed for a partner for a sexually transmitted disease or for a patient's family members if the patient has an illness determined by the Centers for Disease Control and Prevention, the World Health Organization, or the Governor's office to be pandemic;

(viii) instructions for use that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman;

(ix) quantity dispensed;

(x) appropriate ancillary instructions such as storage instructions or cautionary statements such as warnings of potential harmful effects of combining the drug product with any product containing alcohol;

(xi) if the prescription is for a Schedules II - IV controlled substance, the statement "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed";

(xii) if the pharmacist has selected a generically equivalent drug or interchangeable biological product pursuant to the provisions of the Act, Chapter 562, the statement "Substituted for Brand Prescribed" or "Substituted for 'Brand Name'" where "Brand Name" is the actual name of the brand name product prescribed;
(xiii) the name and strength of the actual drug or biological product dispensed that is printed in
an easily readable font size comparable to but no smaller than ten-point Times Roman, unless
otherwise directed by the prescribing practitioner;

(I) The name shall be either:

(-a-) the brand name; or

(-b-) if no brand name, then the generic drug or interchangeable biological product name and
name of the manufacturer or distributor of such generic drug or interchangeable biological
product. (The name of the manufacturer or distributor may be reduced to an abbreviation or
initials, provided the abbreviation or initials are sufficient to identify the manufacturer or
distributor. For combination drug products or non-sterile compounded drug preparations having
no brand name, the principal active ingredients shall be indicated on the label.)

(II) Except as provided in clause (xii) of this subparagraph, the brand name of the prescribed
drug or biological product shall not appear on the prescription container label unless it is the drug
product actually dispensed.

(xiv) if the drug is dispensed in a container other than the manufacturer's original container, the
date after which the prescription should not be used or beyond-use-date. Unless otherwise
specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is
dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may
be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is
not required on the label of a prescription dispensed to a person at the time of release from prison
or jail if the prescription is for not more than a 10-day supply of medication; and

(xv) either on the prescription label or the written information accompanying the prescription,
the statement "Do not flush unused medications or pour down a sink or drain." A drug product
on a list developed by the Federal Food and Drug Administration of medicines recommended for
disposal by flushing is not required to bear this statement.

(B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type
size smaller than ten-point Times Roman, the pharmacy shall provide the patient written
information containing the information as specified in subparagraph (A) of this paragraph in an
easily readable font [size] comparable to but no smaller than ten-point Times Roman.

(C) The label is not required to include the initials or identification code of the dispensing
pharmacist as specified in subparagraph (A) of this paragraph if the identity of the dispensing
pharmacist is recorded in the pharmacy's data processing system. The record of the identity of
the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

(D) The dispensing container is not required to bear the label as specified in subparagraph (A) of
this paragraph if:
(i) the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital);

(ii) no more than a 90-day supply is dispensed at one time;

(iii) the drug is not in the possession of the ultimate user prior to administration;

(iv) the pharmacist-in-charge has determined that the institution:

(I) maintains medication administration records which include adequate directions for use for the drug(s) prescribed;

(II) maintains records of ordering, receipt, and administration of the drug(s); and

(III) provides for appropriate safeguards for the control and storage of the drug(s); and

(v) the dispensing container bears a label that adequately:

(I) identifies the:

(-a-) pharmacy by name and address;

(-b-) unique identification number of the prescription;

(-c-) name and strength of the drug dispensed;

(-d-) name of the patient; and

(-e-) name of the prescribing practitioner or, if applicable, the name of the advanced practice nurse, physician assistant, or pharmacist who signed the prescription drug order;

(II) if the drug is dispensed in a container other than the manufacturer's original container, specifies the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(III) sets forth the directions for use and cautionary statements, if any, contained on the prescription drug order or required by law.

(8) (No change.)

(d) - (i) (No change.)
§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 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) 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 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) Distribution of prescription drugs [controlled substances] to another registrant. A pharmacy may distribute prescription drugs [controlled substances] to a practitioner, another pharmacy, or other registrant, without being registered to distribute, under the following conditions.

(1) If the distribution is for a controlled substance, the registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to possess [dispense] that controlled substance.

(2) The total number of dosage units of prescription drugs [controlled substances] distributed by a pharmacy may not exceed 5.0% of all prescription drugs [controlled substances] dispensed and distributed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute prescription drugs [controlled substances].

(3) If the distribution is for a dangerous drug, a record shall be maintained that indicates the:

(A) date of distribution;

(B) name, strength, and quantity of dangerous drug distributed;

(C) name and address of the distributing pharmacy; and

(D) name and address of the pharmacy, practitioner, or other registrant to whom the dangerous drugs are distributed.

(4) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained that indicates the:

(A) [the actual] date of distribution;

(B) [the] name, strength, and quantity of controlled substances distributed;

(C) [the] name, address, and DEA registration number of the distributing pharmacy; and
(D) [the] name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

(5) [(4)] If the distribution is for a Schedule II controlled substance, the following is applicable.

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

(B) The distributing pharmacy shall:

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

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

(iii) forward Copy 2 of the DEA order form (DEA 222) to the Divisional Office of the Drug Enforcement Administration.

(i) - (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 September 14, 2015.

TRD-201503748

Gay Dodson, R.Ph.

Executive Director

Texas State Board of Pharmacy

Earliest possible date of adoption: October 25, 2015

For further information, please call: (512) 305-8028

461
The Texas State Board of Pharmacy proposes amendments to §291.103 concerning Personnel and §291.104 concerning Operational Standards. The amendments, if adopted, implement provisions of S.B. 460 and HB 751 passed by the 84th Texas Legislature. The amendment to §291.103, if adopted, require the pharmacist-in-charge of a non-resident pharmacy (Class E) to be licensed in Texas. The amendments to §291.104, if adopted, update the requirements with regard to interchangeable biological products and correct grammar.

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 the non-resident pharmacies are supervised by appropriately licensed pharmacists; and pharmacies appropriately dispense interchangeable biological products. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with these sections.

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., October 30, 2015.

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

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

§291.103. Personnel.

As specified in §562.101(f) of the Act (relating to Supervision of Pharmacy), a Class E pharmacy shall be under the continuous on-site supervision of a pharmacist and shall designate one pharmacist licensed to practice pharmacy by the regulatory or licensing agency of the state in which the Class E pharmacy is located and effective September 1, 2016, is licensed as a pharmacist in Texas to serve as the pharmacist-in-charge of the Class E pharmacy license.

§291.104. Operational Standards.
(a) Licensing requirements.

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

(3) On renewal of a license, the pharmacy shall complete the renewal application provided by the board and, as specified in §561.0031 [$561.031] of the Act, provide an inspection report issued not more than three years before the date the renewal application is received and conducted by the pharmacy licensing board in the state of the pharmacy's physical location.

(A) A Class E pharmacy may submit an inspection report issued by an entity other than the pharmacy licensing board of the state in which the pharmacy is physically located if the state's licensing board does not conduct inspections as follows:

(i) an individual approved by the board who is not employed by the pharmacy but acting as a consultant to inspect the pharmacy;

(ii) an agent of the National Association of Boards of Pharmacy;

(iii) an agent of another State Board of Pharmacy; or

(iv) an agent of an accrediting body, such as the Joint Commission on Accreditation of Healthcare Organizations.

(B) The inspection must be substantively equivalent to an inspection conducted by the board.

(4) A Class E pharmacy which changes ownership shall notify the board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(5) A Class E pharmacy which changes location and/or name shall notify the board within ten days of the change and file for an amended license as specified in §291.3 of this title.

(6) A Class E pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures in §291.3 of this title.

(7) A Class E pharmacy shall notify the board in writing within ten days of closing.

(8) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(9) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.
(10) The board may grant an exemption from the licensing requirements of this Act on the
application of a pharmacy located in a state of the United States other than this state that restricts
its dispensing of prescription drugs or devices to residents of this state to isolated transactions.

(11) A Class E pharmacy engaged in the centralized dispensing of prescription drug or
medication orders shall comply with the provisions of §291.125 of this title (relating to
Centralized Prescription Dispensing).

(12) A Class E pharmacy engaged in central processing of prescription drug or medication orders
shall comply with the provisions of §291.123 of this title (relating to Central Prescription or
Medication Order Processing).

(13) A Class E pharmacy engaged in the compounding of non-sterile preparations shall comply
with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile
Preparations).

[(14) Prior to August 31, 2014, a Class E pharmacy engaged in the compounding of sterile
preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies
Compounding Sterile Preparations).]

(14) [(15)] [(Effective August 31, 2014, a) Class E pharmacy personnel] shall not compound
sterile preparations unless the pharmacy has applied for and obtained a Class E-S pharmacy.

(15) [(16)] A Class E pharmacy, which operates as a community type of pharmacy which would
otherwise be required to be licensed under the Act §560.051(a)(1) (Community Pharmacy (Class
A)), shall comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of
this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34
of this title (relating to Records), and §291.35 of this title (relating to Official Prescription
Records), contained in Community Pharmacy (Class A); or which operates as a nuclear type of
pharmacy which would otherwise be required to be licensed under the Act §560.051(a)(2)
(Nuclear Pharmacy (Class B)), shall comply with the provisions of §291.51 of this title (relating
to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to
Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title
(relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are
applicable to the operation of the pharmacy.

(b) (No change.)

(c) [Generic] Substitution requirements.

(1) Unless compliance would violate the pharmacy or drug laws or rules in the state in which the
pharmacy is located a pharmacist in a Class E pharmacy may dispense a generically equivalent
drug or interchangeable biological product and shall comply with the provisions of §309.3 of this
title (relating to [Generic] Substitution Requirements) and §309.7 of this title (relating to
Dispensing Responsibilities).
(2) The pharmacy must include on the prescription order form completed by the patient or the patient's agent information that clearly and conspicuously:

(A) states that if a less expensive generically equivalent drug or interchangeable biological product is available for the brand prescribed, the patient or the patient's agent may choose between the generically equivalent drug or interchangeable biological product and the brand prescribed; and

(B) allows the patient or the patient's agent to indicate the choice of the generically equivalent drug or interchangeable biological product or the brand prescribed.

d) (No change.)

e) Transfer of Prescription Drug Order Information. Unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a Class E pharmacy may not refuse to transfer prescriptions to another pharmacy that is making the transfer request on behalf of the patient. The transfer of original prescription information must be done within four business hours of the request [in a timely manner].

f) (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 September 14, 2015.

TRD-201503753

Gay Dodson, R.Ph.

Executive Director

Texas State Board of Pharmacy

Earliest possible date of adoption: October 25, 2015

For further information, please call: (512) 305-8028
Dear Ms. Benz,

I am writing to follow up with a conversation that I had with Margarita in your office earlier today regarding the proposed rule that amends 22 TAC §§309.1-309.8, relative to the Substitution of Drug Products. The rule appeared in the Texas Register on September 25, 2015 (Volume 40, Number 39) on pages 6545 – 6549.

When I reviewed the rule, I noticed that there were two errors on page 6548, under “§309.4 Patient Notification.” In paragraph (a)(1), the third line should read, “…equivalent drug or interchangeable biological product is available for the…”. In the current draft, the word “or” is omitted. Next, in the fifth line of the same paragraph, it should read, “…between the generically equivalent drug or interchangeable biological product and the…”. In the current draft, the word “interchangeable” is omitted, even though it correctly appears in every other instance referencing ‘interchangeable biological products’ throughout the proposed rule.

I appreciate your consideration and assistance in correcting this paragraph. Please reply to verify receipt of this email, and feel free to also contact me if you have any questions or concerns.

Best regards,
Ritchard Engelhardt

RITCHARD ENGELHARDT
State Director of Government Affairs, Northeastern and Western Regions
Biotechnology Industry Organization
P.202.770.3018|C.415.793.9895|www.bio.org