RULE ANALYSIS

Introduction: THE NEW RULE AND AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED 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.
§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.


2. (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. [43] Electronic prescription drug order--A prescription drug order which is transmitted by an electronic device to the receiver (pharmacy).

6. [44] 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 Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.

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

(11) 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) 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 157.053, [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[s] 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.

(I) 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.

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

(III) 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.”]

(3) A pharmacist shall offer the patient or the patient’s agent the option of paying for a
prescription drug at a lower price instead of paying the amount of the copayment under the
patient’s prescription drug insurance plan if the price of the prescribed drug is lower than the
amount of the patient’s copayment.

(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 subsection (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 as defined in the Subchapter A, Chapter 562 of the Act, the following:

(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.

§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.
§291.33 Operational Standards

(a) – (b) (No change.)

d) 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.

(A) 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 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) – (h) (No change.)
§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 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).]

(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.

(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.)
AN ACT
relating to the prescription and pharmaceutical substitution of
biological products; amending provisions subject to a criminal
penalty.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 562.001, Occupations Code, is amended by
amending Subdivision (1) and adding Subdivisions (1-a) and (1-b) to
read as follows:

(1) "Biological product" has the meaning assigned by
Section 351, Public Health Service Act (42 U.S.C. Section 262).

(1-a) "Generically equivalent" means a drug that is
pharmaceutically equivalent and therapeutically equivalent to the
drug prescribed.

(1-b) "Interchangeable," in reference to a biological
product, has the meaning assigned by Section 351, Public Health
Service Act (42 U.S.C. Section 262), or means a biological product
that is designated as therapeutically equivalent to another product
by the United States Food and Drug Administration in the most recent
dition or supplement of the United States Food and Drug
Administration's Approved Drug Products with Therapeutic
Equivalence Evaluations, also known as the Orange Book.

SECTION 2. Section 562.002, Occupations Code, is amended to
read as follows:

Sec. 562.002. LEGISLATIVE INTENT. It is the intent of the
legislature to save consumers money by allowing 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 and for pharmacies and pharmacists to pass on the net benefit of the lower costs of the generically equivalent drug product or interchangeable biological product to the purchaser.

SECTION 3. Section 562.003, Occupations Code, is amended to read as follows:

Sec. 562.003. DISCLOSURE OF PRICE; PATIENT'S OPTION. If the price of a drug or biological product to a patient is lower than the amount of the patient's copayment under the patient's prescription drug insurance plan, the pharmacist shall offer the patient the option of paying for the drug or biological product at the lower price instead of paying the amount of the copayment.

SECTION 4. Section 562.005, Occupations Code, is amended to read as follows:

Sec. 562.005. RECORD OF DISPENSED DRUG OR BIOLOGICAL PRODUCT. A pharmacist shall record on the prescription form the name, strength, and manufacturer or distributor of a drug or biological product dispensed as authorized by this subchapter.

SECTION 5. Subchapter A, Chapter 562, Occupations Code, is amended by adding Section 562.0051 to read as follows:

Sec. 562.0051. COMMUNICATION REGARDING CERTAIN DISPENSED BIOLOGICAL PRODUCTS. (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.

SECTION 6. Section 562.006, Occupations Code, is amended to read as follows:

Sec. 562.006. LABEL. (a) Unless otherwise directed by the practitioner, the label on the dispensing container must indicate the actual drug or biological product dispensed, indicated by either:

(1) the brand name; or
(2) if there is not a brand name, the drug's generic name or the name of the biological product, the strength of the drug or biological product, and the name of the manufacturer or distributor of the drug or biological product.

(b) In addition to the information required by Subsection (a), the label on the dispensing container of a drug or biological product dispensed by a Class A or Class E pharmacy must indicate:

1. the name, address, and telephone number of the pharmacy;
2. the date the prescription is dispensed;
3. the name of the prescribing practitioner;
4. the name of the patient or, if the drug or biological product was prescribed for an animal, the species of the animal and the name of the owner;
5. instructions for use;
6. the quantity dispensed;
7. if the drug or biological product is dispensed in a container other than the manufacturer's original container, the date after which the prescription should not be used, determined according to criteria established by board rule based on standards in the United States Pharmacopeia-National Formulary; and
8. any other information required by board rule.

(c) The information required by Subsection (b)(7) may be recorded on any label affixed to the dispensing container.

(d) Subsection (b) does not apply to 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.

(e) If a drug or biological product has been selected other than the one prescribed, the pharmacist shall place on the container the words "Substituted for brand prescribed" or "Substituted for 'brand name'" where "brand name" is the name of the brand name drug or biological product prescribed.

(f) The board shall adopt rules requiring the label on a dispensing container to be in plain language and printed in an easily readable font size for the consumer.

SECTION 7. Section 562.008, Occupations Code, is amended to read as follows:

Sec. 562.008. GENERIC EQUIVALENT OR INTERCHANGEABLE BIOLOGICAL PRODUCT AUTHORIZED. (a) If a practitioner certifies on the prescription form that a specific prescribed brand is medically necessary, the pharmacist shall dispense the drug or biological product as written by the practitioner. The certification must be made as required by the dispensing directive adopted under Section 562.015. This subchapter does not permit a pharmacist to substitute a generically equivalent drug or interchangeable biological product unless the substitution is made as provided by this subchapter.

(b) Except as otherwise provided by this subchapter, a pharmacist who receives a prescription for a drug or biological product for which there is one or more generic equivalents or one or more interchangeable biological products may dispense any of the...
generic equivalents or interchangeable biological products.

SECTION 8. The heading to Section 562.009, Occupations Code, is amended to read as follows:

Sec. 562.009. REQUIREMENTS CONCERNING SELECTION OF GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT.

SECTION 9. Sections 562.009(a), (b), (c), and (d), Occupations Code, are amended to read as follows:

(a) Before delivery of a prescription for a generically equivalent drug or interchangeable biological product, a pharmacist must personally, or through the pharmacist's agent or employee:

(1) inform 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

(2) ask the patient or the patient's agent to choose between the generically equivalent drug or interchangeable biological product and the brand prescribed.

(b) A pharmacy is not required to comply with the provisions of Subsection (a):

(1) in the case of the refill of a prescription for which the pharmacy previously complied with Subsection (a) with respect 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) A pharmacy that supplies a prescription by mail is considered to have complied with the provisions of Subsection (a) if the pharmacy includes on the prescription order form completed by the patient or the patient's agent language that clearly and conspicuously:

(1) 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

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

(d) If the patient or the patient's agent fails to indicate otherwise to a pharmacy on the prescription order form under Subsection (c), the pharmacy may dispense a generically equivalent drug or interchangeable biological product.

SECTION 10. Section 562.010, Occupations Code, is amended to read as follows:

Sec. 562.010. RESPONSIBILITY CONCERNING GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT; LIABILITY.

(a) A pharmacist who selects a generically equivalent drug or interchangeable biological product to be dispensed under this
subchapter assumes the same responsibility for selecting the

generically equivalent drug or interchangeable biological product

as the pharmacist does in filling a prescription for a drug

prescribed by generic or biological product name.

(b) The prescribing practitioner is not liable for a

pharmacist's act or omission in selecting, preparing, or dispensing

a drug or biological product under this subchapter.

SECTION 11. Section 562.011, Occupations Code, is amended
to read as follows:

Sec. 562.011. RESTRICTION ON SELECTION OF AND CHARGING FOR

GENERICALLY EQUIVALENT DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT.

(a) A pharmacist may not select a generically equivalent drug or

interchangeable biological product unless the generically

equivalent drug or interchangeable biological product selected

costs the patient less than the prescribed drug or biological

product.

(b) A pharmacist may not charge for dispensing a generically

equivalent drug or interchangeable biological product a

professional fee higher than the fee the pharmacist customarily

charges for dispensing the brand name drug or biological product

prescribed.

SECTION 12. Section 562.013, Occupations Code, is amended
to read as follows:

Sec. 562.013. APPLICABILITY OF SUBCHAPTER. Unless a drug

is determined to be generically equivalent to, or a biological

product is determined to be interchangeable with, the brand

prescribed, drug or biological product selection as authorized by
this subchapter does not apply to:

(1) an enteric-coated tablet;
(2) a controlled release product;
(3) an injectable suspension, other than an antibiotic;
(4) a suppository containing active ingredients for which systemic absorption is necessary for therapeutic activity; or
(5) a different delivery system for aerosol or nebulizer drugs.

SECTION 13. Section 562.015(a), Occupations Code, is amended to read as follows:

(a) The board shall adopt rules to provide a dispensing directive to instruct pharmacists on the manner in which to dispense a drug or biological product according to the contents of a prescription. The rules adopted under this section must:

(1) require the use of the phrase "brand necessary" or "brand medically necessary" on a prescription form to prohibit the substitution of a generically equivalent drug or interchangeable biological product for a brand name drug or biological product;
(2) be in a format that protects confidentiality as required by the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) [(29 U.S.C. Section 1181 et seq.)] and its subsequent amendments;
(3) comply with federal and state law, including rules, with regard to formatting and security requirements;
(4) be developed to coordinate with 42 C.F.R. Section 447.512 [447.131(e)]; and
include an exemption for electronic prescriptions as provided by Subsection (b).

SECTION 14. Subchapter A, Chapter 562, Occupations Code, is amended by adding Section 562.016 to read as follows:

Sec. 562.016. LIST OF APPROVED INTERCHANGEABLE BIOLOGICAL PRODUCTS. The board shall maintain on the board's Internet website a link to the United States Food and Drug Administration's list of approved interchangeable biological products.

SECTION 15. (a) Chapter 562, Occupations Code, as amended by this Act, applies only to a prescription issued for a biological product on or after December 1, 2015. A prescription issued for a biological product before December 1, 2015, is governed by the law in effect immediately before that date, and the former law is continued in effect for that purpose.

(b) The Texas State Board of Pharmacy shall adopt rules necessary to implement the changes in law made by this Act not later than December 1, 2015.

SECTION 16. This Act takes effect September 1, 2015.
H.B. No. 751

I certify that H.B. No. 751 was passed by the House on April 14, 2015, by the following vote: Yeas 146, Nays 0, 1 present, not voting; that the House refused to concur in Senate amendments to H.B. No. 751 on May 8, 2015, and requested the appointment of a conference committee to consider the differences between the two houses; and that the House adopted the conference committee report on H.B. No. 751 on May 21, 2015, by the following vote: Yeas 144, Nays 0, 1 present, not voting.

Chief Clerk of the House
H.B. No. 751

I certify that H.B. No. 751 was passed by the Senate, with amendments, on May 6, 2015, by the following vote: Yeas 31, Nays 0; at the request of the House, the Senate appointed a conference committee to consider the differences between the two houses; and that the Senate adopted the conference committee report on H.B. No. 751 on May 29, 2015, by the following vote: Yeas 31, Nays 0.

______________________________
Secretary of the Senate

APPROVED: __________________
Date

__________________________
Governor
AN ACT

relating to the licensing and regulation of pharmacists and pharmacies.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 483.047, Health and Safety Code, is amended by amending Subsection (a) and adding Subsections (b-1) and (b-2) to read as follows:

(a) Except as authorized by Subsections (b) and (b-1), a pharmacist commits an offense if the pharmacist refills a prescription unless:

(1) the prescription contains an authorization by the practitioner for the refilling of the prescription, and the pharmacist refills the prescription in the manner provided by the authorization; or

(2) at the time of refilling the prescription, the pharmacist is authorized to do so by the practitioner who issued the prescription.

(b-1) Notwithstanding Subsection (b), in the event of a natural or manmade disaster, a pharmacist may dispense not more than a 30-day supply of a dangerous drug without the authorization of the prescribing practitioner if:

(1) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;
the natural or manmade disaster prohibits the pharmacist from being able to contact the practitioner;

(3) the governor has declared a state of disaster under Chapter 418, Government Code; and

(4) the board, through the executive director, has notified pharmacies in this state that pharmacists may dispense up to a 30-day supply of a dangerous drug.

(b-2) The prescribing practitioner is not liable for an act or omission by a pharmacist in dispensing a dangerous drug under Subsection (b-1).

SECTION 2. Section 555.002(a), Occupations Code, is amended to read as follows:

(a) The board by rule shall establish methods by which consumers and service recipients are notified of the name, mailing address, and telephone number of the board for the purpose of directing complaints to the board. The board may provide for that notice:

(1) on each registration form, application, or written contract for services of a person regulated by the board;

(2) on a sign prominently displayed in the place of business of each person regulated by the board; [22]

(3) on an electronic messaging system in a font specified by board rule prominently displayed in the place of business of each person regulated by the board; or

(4) in a bill for service provided by a person regulated by the board.

SECTION 3. Section 556.051, Occupations Code, is amended to
Sec. 556.051. AUTHORIZATION TO ENTER AND INSPECT. (a) The board or a representative of the board may enter and inspect a facility relative to the following:

1. drug storage and security;
2. equipment;
3. components used in compounding, finished and unfinished products, containers, and labeling of any item;
4. sanitary conditions; [or]
5. records, reports, or other documents required to be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws; or
6. subject to Subsection (b), financial records relating to the operation of the facility.

(b) The board or a representative of the board may inspect financial records under Subsection (a) only in the course of the investigation of a specific complaint. The board or representative may inspect only records related to the specific complaint. The inspection is subject to Section 565.055.

SECTION 4. Section 556.054, Occupations Code, is amended to read as follows:

Sec. 556.054. CONFIDENTIALITY OF CERTAIN INFORMATION [LIMITATION ON INSPECTION]. The following information obtained by the board during an inspection of a facility is confidential and not subject to disclosure under Chapter 552, Government Code [Unless
the owner, pharmacist, or agent in charge of a facility consents in
writing, an inspection of the facility authorized by this chapter
may not extend to:

(1) financial data;
(2) sales data, other than shipment data; and
(3) pricing data.

SECTION 5. Subchapter B, Chapter 556, Occupations Code, is
amended by adding Section 556.057 to read as follows:

Sec. 556.057. INSPECTION OF PHARMACIST RECORDS. A
pharmacist shall provide to the board, on request, records of the
pharmacist's practice that occurs outside of a pharmacy. The
pharmacist shall provide the records at a time specified by board
rule.

SECTION 6. Sections 558.055(a) and (b), Occupations Code, are
amended to read as follows:

(a) An applicant who on the applicant's first attempt fails
the examination may take the examination four [two] additional
times.

(b) Before an applicant who has failed the examination five
[three] times is allowed to retake the examination, the applicant
must provide documentation from a college of pharmacy that the
applicant has successfully completed additional college course
work in each examination subject area the applicant failed.

SECTION 7. Section 560.052(b), Occupations Code, is amended
to read as follows:

(b) To qualify for a pharmacy license, an applicant must
submit to the board:
(1) a license fee set by the board, except as provided by Subsection (d); and

(2) a completed application that:

(A) is on a form prescribed by the board;

(B) is given under oath;

(C) includes proof that:

(i) a pharmacy license held by the applicant in this state or another state, if applicable, has not been restricted, suspended, revoked, or surrendered for any reason;

and

(ii) no owner of the pharmacy for which the application is made has held a pharmacist license in this state or another state, if applicable, that has been restricted, suspended, revoked, or surrendered for any reason; and

(D) includes a statement of:

(i) the ownership;

(ii) the location of the pharmacy;

(iii) the license number of each pharmacist who is employed by the pharmacy, if the pharmacy is located in this state, or who is licensed to practice pharmacy in this state, if the pharmacy is located in another state;

(iv) the pharmacist license number of the pharmacist-in-charge; and

(v) any other information the board determines necessary.

SECTION 8. Section 561.003(e), Occupations Code, is amended to read as follows:
If a pharmacy's license has been expired for 91 days or more, the pharmacy may not renew the license. The pharmacy may obtain a new license by complying with the requirements and procedures for obtaining an original license.

SECTION 9. Sections 562.056(a) and (a-1), Occupations Code, are amended to read as follows:

(a) Before dispensing a prescription, a pharmacist shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. A pharmacist may not dispense a prescription drug if the pharmacist knows or should know that the prescription was issued [on the basis of an Internet-based or telephonic consultation] without a valid practitioner-patient relationship.

(a-1) To be a valid prescription, a prescription [for a controlled substance] must be issued for a legitimate medical purpose by a practitioner acting in the usual course of the practitioner's professional practice. The responsibility for the proper prescribing and dispensing of prescription drugs [controlled substances] is on the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

SECTION 10. Section 562.106, Occupations Code, is amended by amending Subsection (a) and adding Subsection (a-1) to read as follows:

(a) A pharmacy shall report in writing to the board not later than the 10th day after the date of:

(1) a permanent closing of the pharmacy;
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(2) a change of ownership of the pharmacy;

(3) [a change of location of the pharmacy;]

[4(a)] a change of the person designated as the pharmacist-in-charge of the pharmacy;

(4) [4(a)] a sale or transfer of any controlled substance or dangerous drug as a result of the permanent closing or change of ownership of the pharmacy;

[5(a)] any matter or occurrence that the board requires by rule to be reported;

[6(a)] as determined by the board, an out-of-state purchase of any controlled substance;

[7(a)] a final order against the pharmacy license holder by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state; or

[8(a)] a final order against a pharmacist who is designated as the pharmacist-in-charge of the pharmacy by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state.

(a-1) A pharmacy shall report in writing to the board not later than the 30th day before the date of a change of location of the pharmacy.

SECTION 11. Section 565.002(a), Occupations Code, is amended to read as follows:

(a) The board may discipline an applicant for or the holder of a pharmacy license, including a Class E pharmacy license subject to Section 565.003 [565.003(a)], if the board finds that the
applicant or license holder has:

(1) been convicted of or placed on deferred adjudication community supervision or deferred disposition or the applicable federal equivalent for:

(A) a misdemeanor:
   (i) involving moral turpitude; or
   (ii) under Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.); or

(B) a felony;

(2) advertised a prescription drug or device in a deceitful, misleading, or fraudulent manner;

(3) violated any provision of this subtitle or any rule adopted under this subtitle or that an owner or employee of a pharmacy has violated any provision of this subtitle or any rule adopted under this subtitle;

(4) sold without legal authorization a prescription drug or device to a person other than:

(A) a pharmacy licensed by the board;

(B) a practitioner;

(C) a person who procures a prescription drug or device for lawful research, teaching, or testing, and not for resale;

(D) a manufacturer or wholesaler licensed by the commissioner of public health as required by Chapter 431, Health and Safety Code; or

(E) a carrier or warehouseman;
(5) allowed an employee who is not a pharmacist to practice pharmacy;
(6) sold an adulterated or misbranded prescription or nonprescription drug;
(7) failed to engage in or ceased to engage in the business described in the application for a license;
(8) failed to maintain records as required by this subtitle, Chapter 481 or 483, Health and Safety Code, the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.), or any rule adopted under this subtitle or Chapter 483, Health and Safety Code;
(9) failed to establish and maintain effective controls against diversion of prescription drugs into other than a legitimate medical, scientific, or industrial channel as provided by this subtitle, another state statute or rule, or a federal statute or rule;
(10) engaged in fraud, deceit, or misrepresentation as defined by board rule in operating a pharmacy or in applying for a license to operate a pharmacy;
(11) violated a disciplinary order;
(12) been responsible for a drug audit shortage; [or]
(13) been disciplined by the regulatory board of another state for conduct substantially equivalent to conduct described under this subsection; or
(14) waived, discounted, or reduced, or offered to waive, discount, or reduce, a patient copayment or deductible for a compounded drug in the absence of:
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(A) a legitimate, documented financial hardship

of the patient; or

(B) evidence of a good faith effort to collect

the copayment or deductible from the patient.

SECTION 12. Section 565.060(d), Occupations Code, is amended to read as follows:

(d) If a license holder complies with and successfully completes the terms of a remedial plan, the board shall remove all records of the remedial plan from the board's records at the end of the state fiscal year in which [on the fifth anniversary of the date the board issued the terms of the remedial plan occurs.]

SECTION 13. Section 565.061(a), Occupations Code, is amended to read as follows:

(a) Except as provided by Chapter 564, a disciplinary action taken by the board [under Section 565.060 or] on the basis of a ground for discipline under Subchapter A is governed by Chapter 2001, Government Code, and the rules of practice and procedure before the board.

SECTION 14. The following provisions of the Occupations Code are repealed:

(1) Section 561.003(d);

(2) Section 562.009(a-1); and

(3) Section 562.051.

SECTION 15. The change in law made by this Act to Section 483.047, Health and Safety Code, applies only to an offense committed on or after the effective date of this Act. An offense committed before the effective date of this Act is governed by the
law in effect on the date the offense was committed, and the former law is continued in effect for that purpose. For purposes of this section, an offense was committed before the effective date of this Act if any element of the offense occurred before that date.

SECTION 16. Section 560.052(b), Occupations Code, as amended by this Act, applies only to an application for a pharmacy license submitted on or after the effective date of this Act. An application submitted before the effective date of this Act is governed by the law in effect on the date the application was submitted, and the former law is continued in effect for that purpose.

SECTION 17. Section 561.003(e), Occupations Code, as amended by this Act, and the repeal by this Act of Section 561.003(d), Occupations Code, apply only to a pharmacy license that expires on or after the effective date of this Act. A pharmacy license that expired before the effective date of this Act is governed by the law in effect on the date the license expired, and the former law is continued in effect for that purpose.

SECTION 18. Section 562.106(a), Occupations Code, as added by this Act, and Section 562.106(a-1), Occupations Code, as added by this Act, apply only to a pharmacy that changes location on or after October 1, 2015. A pharmacy that changes location before that date is governed by the law in effect immediately before the effective date of this Act, and the former law is continued in effect for that purpose.

SECTION 19. The change in law made by this Act to Section 565.002(a), Occupations Code, applies only to conduct that occurs
on or after the effective date of this Act. Conduct that occurs
before that date is governed by the law in effect on the date the
conduct occurred, and the former law is continued in effect for that
purpose.

SECTION 20. The change in law made by this Act to Section
565.061(a), Occupations Code, is a clarification of existing law
and does not imply that existing law may be construed as
inconsistent with the law as amended by this Act.

SECTION 21. This Act takes effect September 1, 2015.
President of the Senate

I hereby certify that S.B. No. 460 passed the Senate on April 14, 2015, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

I hereby certify that S.B. No. 460 passed the House on May 22, 2015, by the following vote: Yeas 137, Nays 3, two present not voting.

Chief Clerk of the House

Approved:

Date

Governor