RULE ANALYSIS

Introduction: **THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED RULE**

Short Title: Telepharmacy

Rule Numbers: §291.121

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;
(2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act; and
(3) Section 562.110 gives the Board the authority to adopt rules for telepharmacies.

Purpose: The amendments, if adopted, implement SB 1633 and portions of HB 2561 relating to telepharmacy as passed by the 85th Texas Legislature.

TITLE 22 EXAMINING BOARDS
PART 15 TEXAS STATE BOARD OF PHARMACY
CHAPTER 291 PHARMACIES
SUBCHAPTER G SERVICES PROVIDED BY PHARMACIES

§291.121 Remote Pharmacy Services

(a) Remote pharmacy services using automated pharmacy systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an automated pharmacy system as outlined in §562.109 of the Texas Pharmacy Act.

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

(A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and maintains related transaction information.

(B) Remote site--A facility not located at the same location as a Class A or Class C pharmacy, at which remote pharmacy services are provided using an automated pharmacy dispensing system.

(C) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container, or quantities of unit dosed drugs, into another cartridge or container for dispensing by a pharmacist using an automated pharmacy system.

(D) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.

(E) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, in remote sites.

(F) Unit dose--An amount of a drug packaged in a dosage form ready for administration to a particular patient, by the prescribed route at the prescribed time, and properly labeled with name, strength, and expiration date of the drug.

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using an automated pharmacy system to a jail or prison operated by or for the State of Texas, a jail or prison operated by local government or a healthcare facility regulated under Chapter 142, 242, 247, or 252, Health and Safety Code, provided drugs are administered by a licensed healthcare professional working in the jail, prison, or healthcare facility.

(B) A provider pharmacy may only provide remote pharmacy services using an automated pharmacy system to inpatients of the remote site.

(C) A provider pharmacy may provide remote pharmacy services at more than one remote site.

(D) Before providing remote pharmacy services, the automated pharmacy system at the remote site must be tested by the provider pharmacy and found to dispense accurately. The provider pharmacy shall make the results of such testing available to the board upon request.

(E) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel, Operational Standards, and Records for Class A (Community) Pharmacies) and this section.

(F) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the automated pharmacy system located at the remote site including supervision of the automated pharmacy system and compliance with this section.

(G) A pharmacist from the provider pharmacy shall be accessible at all times to respond to patient's or other health professionals' questions and needs pertaining to drugs dispensed through the use of the automated pharmacy system. Such access may be through a 24 hour pager service or telephone which is answered 24 hours a day.

(4) Operational standards.

(A) Application for permission to provide pharmacy services using an automated pharmacy system.

(i) A Class A or Class C Pharmacy shall **file a completed application containing all information required by** [~~make application to~~] the board to provide remote pharmacy services using an automated pharmacy system. [~~The application shall contain an affidavit with the notarized signatures of the pharmacist-in-charge, and the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, chief operating officer, owner, chief executive officer), and include the following:~~]

~~[(I) the name, address, and license number of the provider pharmacy;~~

~~(II) name and address of the facility where the remote pharmacy services will be provided;~~

~~(III) a statement indicating that the provider pharmacy and the facility have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations; and~~

~~(IV) documentation that the automated pharmacy system is located where medications are administered by license healthcare professionals and is:~~

~~(-a-) a facility regulated under Chapter 142, 242, 247, or 252, Health and Safety Code; or~~

~~(-b-) a jail or prison, operated by the State of Texas or local government.]~~

(ii) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license. [~~The renewal petition shall contain the documentation required in clause (i) of this subparagraph except the notarized signature of the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, chief operating officer, owner, chief executive officer) is not required.~~]

(iii) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the remote site.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a [~~change of location,~~] discontinuance of service, or closure of:

(I) a remote site where an automated pharmacy system is operated by the pharmacy; or

(II) a remote pharmacy service at a remote site.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site if controlled substances are maintained within an automated pharmacy system at the facility.

(iii) A provider pharmacy shall file a change of location and/or name of a remote site as specified in §291.3 (relating to Notifications) of this title.

(C) Environment/Security.

(i) A provider pharmacy shall only store drugs at a remote site within an automated pharmacy system which is locked by key, combination or other mechanical or electronic means so as to prohibit access by unauthorized personnel.

(ii) An automated pharmacy system shall be under the continuous supervision of a provider pharmacy pharmacist. To qualify as continuous supervision, the pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is supervised electronically by a pharmacist.

(iii) Automated pharmacy systems shall have adequate security and procedures to:

(I) comply with federal and state laws and regulations; and

(II) maintain patient confidentiality.

(iv) Access to the automated pharmacy system shall be limited to pharmacists or personnel who:

(I) are designated in writing by the pharmacist-in-charge; and

(II) have completed documented training concerning their duties associated with the automated pharmacy system.

(v) Drugs shall be stored in compliance with the provisions of §291.15 of this title (relating to Storage of Drugs) and §291.33(f)(2) of this title including the requirements for temperature and handling of outdated drugs.

(D) Prescription dispensing and delivery.

(i) Drugs shall only be dispensed at a remote site through an automated pharmacy system after receipt of an original prescription drug order by a pharmacist at the provider pharmacy in a manner authorized by §291.34(b) of this title.

(ii) A pharmacist at the provider pharmacy shall control all operations of the automated pharmacy system and approve the release of the initial dose of a prescription drug order. Subsequent doses from an approved prescription drug order may be removed from the

automated medication system after this initial approval. Any change made in the prescription drug order shall require a new approval by a pharmacist to release the drug.

(iii) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified in §291.33(c) of this title prior to releasing a prescription drug order to the automated pharmacy system.

(iv) Drugs dispensed by the provider pharmacy through an automated pharmacy system shall comply with the labeling or labeling alternatives specified in §291.33(c) of this title.

(v) An automated pharmacy system used to meet the emergency medication needs for residents of a remote site must comply with the requirements for emergency medication kits in subsection (b) of this section.

(E) Drugs.

(i) Drugs for use in an automated pharmacy system shall be packaged in the original manufacturer's container or be prepackaged in the provider pharmacy and labeled in compliance with the board's prepackaging requirements for the class of pharmacy.

(ii) Drugs dispensed from the automated pharmacy system may be returned to the pharmacy for reuse provided the drugs are in sealed, tamper evident packaging which has not been opened.

(F) Stocking an automated pharmacy system.

(i) Stocking of drugs in an automated pharmacy system shall be completed by a pharmacist, pharmacy technician, or pharmacy technician trainee under the direct supervision of a pharmacist, except as provided in clause (ii) of this subparagraph.

(ii) If the automated pharmacy system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers shall occur at the provider pharmacy unless provided by an FDA approved repackager. The prepackaged cartridges or containers may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(I) a pharmacist verifies the cartridge or container has been properly filled and labeled;

(II) the individual cartridges or containers are transported to the remote site in a secure, tamper-evident container; and

(III) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure that the containers are accurately loaded in the automated pharmacy system.

(iii) All drugs to be stocked in the automated pharmacy system shall be delivered to the remote site by the provider pharmacy.

(G) Quality assurance program. A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to a written program for quality assurance of the automated pharmacy system which:

(i) requires continuous supervision of the automated pharmacy system; and

(ii) establishes mechanisms and procedures to routinely test the accuracy of the automated pharmacy system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(H) Policies and procedures of operation.

(i) A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) a current list of the name and address of the pharmacist-in-charge and personnel designated by the pharmacist-in-charge to have access to the drugs stored in the automated pharmacy system;

(II) duties which may only be performed by a pharmacist;

(III) a copy of the portion of the written contract or agreement between the pharmacy and the facility which outlines the services to be provided and the responsibilities and accountabilities of each party relating to the operation of the automated pharmacy system in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

(IV) date of last review/revision of the policy and procedure manual; and

(V) policies and procedures for:

(-a-) security;

(-b-) operation of the automated pharmacy system;

(-c-) preventative maintenance of the automated pharmacy system;

(-d-) sanitation;

(-e-) storage of drugs;

(-f-) dispensing;

(-g-) supervision;

(-h-) drug procurement;

(-i-) receiving of drugs;

(-j-) delivery of drugs; and

(-k-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an automated pharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of the automated pharmacy system to dispense prescription drugs. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated pharmacy system is experiencing downtime;

(II) procedures for response when an automated pharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(ii) The provider pharmacy shall maintain original prescription drug orders for drugs dispensed from an automated pharmacy system in compliance with §291.34(b) of this title.

(iii) if prescription drug records are maintained in a data processing system, the system shall have a workable (electronic) data retention system which can produce a separate audit trail of drug usage by the provider pharmacy and each remote site for the preceding two years as specified in §291.34(e) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Records of dispensing. Dispensing records for a prescription drug order shall be maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(D) Transaction information.

(i) The automated pharmacy system shall electronically record all transactions involving drugs stored in, removed, or dispensed from the system.

(ii) Records of dispensing from an automated pharmacy system for a patient shall be maintained by the providing pharmacy and include the:

(I) identity of the system accessed;

(II) identification of the individual accessing the system;

(III) date of transaction;

(IV) name, strength, dosage form, and quantity of drug accessed; and

(V) name of the patient for whom the drug was accessed.

(iii) Records of stocking or removal from an automated pharmacy system shall be maintained by the pharmacy and include the:

(I) date;

(II) name, strength, dosage form, and quantity of drug stocked or removed;

(III) name, initials, or identification code of the person stocking or removing drugs from the system;

(IV) name, initials, or identification code of the pharmacist who checks and verifies that the system has been accurately filled;

(E) Patient medication records. Patient medication records shall be created and maintained by the provider pharmacy in the manner required by §291.34(c) of this title.

(F) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the records of the provider pharmacy and from any other remote site's records; and

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title (relating to Inventory Requirements for All Classes of Pharmacies) that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs of the provider pharmacy.

(b) Remote pharmacy services using emergency medication kits.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an emergency medication kit as outlined in §562.108 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this subsection, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and maintains related transaction information.

(B) Emergency medication kits--Controlled substances and dangerous drugs maintained by a provider pharmacy to meet the emergency medication needs of a resident:

(i) at an institution licensed under Chapter 242 or 252, Health and Safety Code; or

(ii) at an institution licensed under Chapter 242, Health and Safety Code and that is a veterans home as defined by the §164.002, Natural Resources Code, if the provider pharmacy is a United States Department of Veterans Affairs pharmacy or another federally operated pharmacy.

(C) Remote site--A facility not located at the same location as a Class A, Class C, Class E pharmacy or a United States Department of Affairs pharmacy or another federally operated pharmacy, at which remote pharmacy services are provided using an emergency medication kit.

(D) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container, or quantities of unit dosed drugs, into another cartridge or container for dispensing by a pharmacist using an emergency medication kit.

(E) Provider pharmacy--The community pharmacy (Class A), the institutional pharmacy (Class C), the non-resident (Class E) pharmacy located not more than 20 miles from an institution licensed under Chapter 242 or 252, Health and Safety Code, or the United States Department of Veterans Affairs pharmacy or another federally operated pharmacy providing remote pharmacy services.

(F) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, in remote sites.

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using an emergency medication kit to an institution regulated under Chapter 242, or 252, Health and Safety Code.

(B) A provider pharmacy may provide remote pharmacy services at more than one remote site.

(C) A provider pharmacy shall not place an emergency medication kit in a remote site which already has a kit from another provider pharmacy except as provided by paragraph (4)(B)(iii) of this subsection.

(D) A provider pharmacy which is licensed as an institutional (Class C) or a non-resident (Class E) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this section.

(E) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the emergency medication kit located at the remote site including supervision of the emergency medication kit and compliance with this section.

(4) Operational standards.

(A) Application for permission to provide pharmacy services using an emergency medication kit.

(i) A Class A, Class C, or Class E Pharmacy shall **file a completed application containing all information required by** [~~make application to~~] the board to provide remote pharmacy services using an emergency medication kit. [~~The application shall contain an affidavit with the notarized signatures of the pharmacist-in-charge, and the medical director or the person~~

~~responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief operating officer), and include the following:~~

~~(I) the name, address, and license number of the provider pharmacy;~~

~~(II) name and address of the healthcare facility where the remote pharmacy services will be provided;~~

~~(III) a statement indicating that the provider pharmacy and the healthcare facility have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations;~~

~~(IV) documentation that the emergency medication kit is located in a facility regulated under Chapter 242, or 252, Health and Safety Code; and~~

~~(V) if applicable, documentation that the emergency kit is located in a facility that is not more than 20 miles from the Class E pharmacy providing the emergency kit~~.]

(ii) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license. [~~The renewal petition shall contain the documentation required in clause (i) of this subparagraph except the notarized signature of the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief operating officer) is not required.~~]

(iii) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the remote site.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a [~~change of location,~~] discontinuance of service, or closure of:

(I) a remote site where an emergency medication kit is operated by the pharmacy; or

(II) a remote pharmacy service at a remote site.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site if controlled substances are maintained within an emergency medication kit at the facility.

(iii) If more than one provider pharmacy provides an emergency kit to a remote site, the provider pharmacies must enter into a written agreement as to the emergency medications supplied by each pharmacy. The provider pharmacies shall not duplicate drugs stored in the emergency medication kits. The written agreement shall include reasons why an additional pharmacy is required to meet the emergency medication needs of the residents of the institution.

(iv) A provider pharmacy shall file a change of location and/or name of a remote site as specified in §291.3 of this title.

(C) Environment/Security.

(i) Emergency medication kits shall have adequate security and procedures to:

(I) prohibit unauthorized access;

(II) comply with federal and state laws and regulations; and

(III) maintain patient confidentiality.

(ii) Access to the emergency medication kit shall be limited to pharmacists and licensed healthcare personnel employed by the facility.

(iii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of this title including the requirements for temperature and handling outdated drugs.

(D) Prescription dispensing and delivery.

(i) Drugs in the emergency medication kit shall be accessed for administration to meet the emergency medication needs of a resident of the remote site pursuant to an order from a practitioner. The prescription drug order for the drugs used from the emergency medication kit shall be forwarded to the provider pharmacy in a manner authorized by §291.34(b) of this title.

(ii) The remote site shall notify the provider pharmacy of each entry into an emergency medication kit. Such notification shall meet the requirements of paragraph (5)(D)(ii) of this subsection.

(E) Drugs.

(i) The contents of an emergency medication kit:

(I) may consist of dangerous drugs and controlled substances; and

(II) shall be determined by the consultant pharmacist, pharmacist-in-charge of the provider pharmacy, medical director, and the director of nurses and limited to those drugs necessary to meet the resident's emergency medication needs. For the purpose of this subsection, this shall mean a situation in which a drug cannot be supplied by a pharmacy within a reasonable time period.

(ii) When deciding on the drugs to be placed in the emergency medication kit, the consultant pharmacist, pharmacist-in-charge of the provider pharmacy, medical director, and the director of nurses must determine, select, and record a prudent number of drugs for potential emergency incidents based on:

(I) clinical criteria applicable to each facility's demographics;

(II) the facility's census; and

(III) the facility's healthcare environment.

(iii) A current list of the drugs stored in each remote site's emergency medication kit shall be maintained by the provider pharmacy and a copy kept with the emergency medication kit.

(iv) An automated pharmacy system may be used as an emergency medication kit provided the system limits emergency access to only those drugs approved for the emergency medication kit.

(v) Drugs for use in an emergency medication kit shall be packaged in the original manufacturer's container or prepackaged in the provider pharmacy and labeled in compliance with the board's prepackaging requirements for the class of pharmacy.

(F) Stocking emergency medication kits.

(i) Stocking of drugs in an emergency medication kit shall be completed at the provider pharmacy or remote site by a pharmacist, pharmacy technician, or pharmacy technician trainee under the direct supervision of a pharmacist, except as provided in clause (ii) of this subparagraph.

(ii) If the emergency medication kit is an automated pharmacy system which uses bar-coding, microchip, or other technologies to ensure that the containers or unit dose drugs are accurately loaded, the prepackaging of the containers or unit dose drugs shall occur at the provider pharmacy unless provided by a FDA approved repackager. The prepackaged containers or unit dose drugs may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(I) a pharmacist verifies the container or unit dose drug has been properly filled and labeled;

(II) the individual containers or unit dose drugs are transported to the remote site in a secure, tamper-evident container; and

(III) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure that the containers or unit dose drugs are accurately loaded in the automated pharmacy system.

(iii) All drugs to be stocked in the emergency medication kit shall be delivered to the remote site by the provider pharmacy.

(G) Policies and procedures of operation.

(i) A provider pharmacy that provides pharmacy services through an emergency medication kit at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) duties which may only be performed by a pharmacist;

(II) a copy of the written contract or agreement between the pharmacy and the facility which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

(III) date of last review/revision of the policy and procedure manual; and

(IV) policies and procedures for:

(-a-) security;

(-b-) operation of the emergency medication kit;

(-c-) preventative maintenance of the automated pharmacy system if the emergency medication kit is an automated pharmacy system;

(-d-) sanitation;

(-e-) storage of drugs;

(-f-) dispensing;

(-g-) supervision;

(-h-) drug procurement;

(-i-) receiving of drugs;

(-j-) delivery of drugs; and

(-k-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through an emergency medication kit at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an emergency medication kit which is an automated pharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of the automated pharmacy system to provide emergency medications. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated pharmacy system is experiencing downtime;

(II) procedures for response when an automated pharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(ii) The provider pharmacy shall maintain original prescription drug orders for drugs dispensed from an emergency medication kit in compliance with §291.34(b) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Records of dispensing. Dispensing records for a prescription drug order shall be maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(D) Transaction information.

(i) A prescription drug order shall be maintained by the provider pharmacy as the record of removal of a drug from an emergency medication kit for administration to a patient.

(ii) The remote site shall notify the provider pharmacy electronically or in writing of each entry into an emergency medication kit. Such notification may be included on the prescription drug order or a separate document and shall include the name, strength, and quantity of the drug removed, the time of removal, and the name of the person removing the drug.

(iii) A separate record of stocking, removal, or dispensing for administration from an emergency medication kit shall be maintained by the pharmacy and include the:

(I) date;

(II) name, strength, dosage form, and quantity of drug stocked, removed, or dispensed for administration;

(III) name, initials, or identification code of the person stocking, removing, or dispensing for administration, drugs from the system;

(IV) name, initials, or identification code of the pharmacist who checks and verifies that the system has been accurately filled; and

(V) unique prescription number assigned to the prescription drug order when the drug is administered to the patient.

(E) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the records of the provider pharmacy and from any other remote site's records; and

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title, that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs of the provider pharmacy.

(c) Remote pharmacy services using telepharmacy systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a healthcare facility that is not at the same

location as a Class A or Class C pharmacy through a telepharmacy system as outlined in §562.110 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

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

~~[(B)]~~ Provider pharmacy—

(i) **a Class A pharmacy that provides pharmacy services through a telepharmacy system at a remote dispensing site or at a healthcare facility that is regulated by this state or the United States; or**

(ii) a Class C pharmacy that provides pharmacy services though a telepharmacy system at a healthcare facility that is regulated by this state or the United States.[~~The community pharmacy (Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.~~]

(B) Remote dispensing site-- a location licensed as a telepharmacy that is authorized by a provider pharmacy through a telepharmacy system to store and dispense prescription drugs and devices, including dangerous drugs and controlled substances.

~~[(C) Remote site--a facility not located at the same location as a Class A or Class C pharmacy, at which remote pharmacy services are provided using a telepharmacy dispensing system.~~]

(C) Remote healthcare site—a healthcare facility regulated by this state or the United States that is a:

(i) rural health clinic regulated under 42 U.S.C. Section 1395x(aa);

(ii) health center as defined by 42 U.S.C. Section 254b;

(iii) healthcare facility located in a medically underserved area as determined by the United States Department of Health and Human Services; or

(iv) healthcare facility located in a health professional shortage area as determined by the United States Department of Health and Human Services.

(D) Remote site—a remote healthcare site or a remote dispensing site.

(E) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, drug regimen review, and patient counseling, at a remote site.

(F) ~~[(E)]~~ Still image capture--A specific image captured electronically from a video or other image capture device.

(G) ~~[(F)]~~ Store and forward--A video or still image record which is saved electronically for future review.

(H) [~~(G)~~] Telepharmacy system--A system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method which shall include the use of the following types of technology:

(i) audio and video;

(ii) still image capture; and

(iii) store and forward.

[~~(H) Unit-of-use--A sufficient quantity of a drug for one normal course of therapy as determined by the pharmacist-in-charge and the prescribing practitioner(s) at the healthcare facility.~~]

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using a telepharmacy system **at a** [~~to~~]:

(i) **remote healthcare site; or** [~~a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended~~];

(ii) **remote dispensing site.** [~~a health center as defined by 42 U.S.C. Section 254b, as amended; or~~]

[~~(iii) healthcare facility located in a medically underserved area as defined by state or federal law~~]

(B) A provider pharmacy may not provide remote pharmacy services **at a remote healthcare site** if a Class A [~~(Community)~~] or Class C [~~(Institutional)~~] pharmacy that dispenses prescription drug orders to out-patients is located in the same community. For the purposes of this subsection a community is defined as:

(i) the census tract in which the remote site is located, if the remote site is located in a Metropolitan Statistical Area (MSA) as defined by the United States Census Bureau in the most recent U.S. Census; or

(ii) within 10 miles of the remote site, if the remote site is not located in a MSA.

(C) **A provider pharmacy may not provide remote pharmacy services at a remote dispensing site if a Class A pharmacy is located:**

(i) within 25 miles by road of the remote dispensing site; or

(ii) if located in a county with a population of at least 13,000 but not more than 14,000, within 22 miles by road of the dispensing site. [~~The provider pharmacy shall have sufficient pharmacists on duty such that each pharmacist may supervise no more three remote sites that are simultaneously open to provide services. An exception to the supervision limit may be granted by the board in situations where the provider has documented a need for a pharmacist to supervise additional remote sites and has demonstrated that appropriate safeguards are in place to assure proper supervision of each remote site.~~]

(D) **If a Class A or Class pharmacy is established in a community in which a remote healthcare site has been located, the remote healthcare site may continue to operate.**

(E) If a Class A pharmacy is established within 25 miles by road of a remote dispensing site that is currently operating, or 22 miles by road of a remote site in a county with a population of at least 13,000 but not more than 14,000, the remote dispensing site may continue to operate at that location.

(F) Before providing remote pharmacy **services** [~~service~~], the telepharmacy system at the **remote site** [~~off-site facility~~] must be tested by the provider pharmacy and found to operate properly. The provider pharmacy shall make the results of such testing available to the board upon request.

(G) [~~(E)~~] A provider pharmacy which is licensed as **a Class C** [~~an institutional (Class C)~~] pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this section.

[~~(F) The pharmacist-in-charge of the provider pharmacy is responsible for all operations at the remote site including supervision of the telepharmacy system and compliance with this section.~~]

(4) **Personnel.**

(A) The pharmacist-in-charge of the provider pharmacy is responsible for all operations at the remote site including supervision of the telepharmacy system and compliance with this section.

(B) The provider pharmacy shall have sufficient pharmacists on duty such that each pharmacist may supervise no more two remote sites that are simultaneously open to provide services.

(C) The following duties shall be performed only by a pharmacist at the provider pharmacy:

(I) receiving an oral prescription drug order;

(II) interpreting the prescription drug order;

(III) verifying the accuracy of prescription data entry;

(IV) selecting the drug product to be stored and dispensed at the remote site;

(V) interpreting the patient's medication record and conducting a drug regimen review;

(VI) authorizing the telepharmacy system to print a prescription label at the remote site;

(VII) performing the final check of the dispensed prescription to ensure that the prescription drug order has been dispensed accurately as prescribed; and

(VIII) counseling the patient.

(5) Operational standards.

(A) Application to provide **remote** pharmacy services using a telepharmacy system.

(i) A Class A or class C Pharmacy shall **file a completed application containing all information required by** [~~make application to~~] the board to provide remote pharmacy services using a telepharmacy system. [~~The application shall contain an affidavit with the notarized signatures of pharmacist-in-charge, and the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief operating officer), and include the following:~~]

[~~(I) the name, address, and license number of the provider pharmacy;~~

~~(II) name and address of the healthcare facility where the remote pharmacy services will be provided;~~

~~(III) a statement indicating that the provider pharmacy and the healthcare facility have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations;~~

~~(IV) documentation that the healthcare facility is:~~

~~(-a-) a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended];~~

~~(-b-) a health center as defined by 42 U.S.C. Section 254b, as amended; or]~~

~~(-c-) located in a medically underserved area as defined by state or federal law; and]~~

~~(V) documentation that a Class A (Community) or Class C (Institutional) Pharmacy that dispenses prescriptions drug orders to out-patients is not located within the community, as defined in paragraph (3)(B) of this subsection, where the remote site is located.~~]

(ii) Such application shall be resubmitted every two years in conjunction with the renewal of the provider pharmacy's license. [~~The renewal application shall contain the documentation required in clause (i) of this subparagraph except the notarized signature of the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief operating officer) is not required.~~]

(iii) On approval of the application, the provider pharmacy will be sent a **license for the remote site** [~~registration certificate~~], which must be displayed at the remote site.

(iv) If the average number of prescriptions dispensed each day at a remote dispensing site is open for business is more than 125 prescriptions, as calculated each calendar year, the remote dispensing site shall apply for a Class A pharmacy license as specified in §291.1 of this title (relating to Pharmacy License Application).

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a [~~change of location,~~] discontinuance of service, or closure of[~~:~~]

[~~(I)~~] a remote site where a telepharmacy system is operated by the pharmacy[~~; or~~

~~(II) a remote pharmacy service at a remote site~~].

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site, if controlled substances are maintained.

(iii) A provider pharmacy shall file a change of location and/or name of a remote site as specified in §291.3 of this title.

(C) Environment/Security.

(i) A remote site shall be under the continuous supervision of a provider pharmacy pharmacist at all times the site is open to provide pharmacy services. To qualify as continuous supervision, the pharmacist is not required to be physically present at the remote site and shall supervise electronically through the use of the following types of technology:

(I) audio and video;

(II) still image capture; and

(III) store and forward.

(ii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of this title including the requirements for temperature and handling of outdated drugs.

(iii) Drugs for use in the telepharmacy system **at a remote healthcare site** shall be stored in an area that is:

(I) separate from any other drugs used by the healthcare facility; and

(II) locked by key, combination or other mechanical or electronic means, so as to prohibit access by unauthorized personnel.

(iv) **Drugs for use in the telepharmacy system at a remote dispensing site shall be stored in an area that is locked by key, combination, or other mechanical or electronic means, so as to prohibit access by unauthorized personnel.**

(v) Access to the area where drugs are stored at the remote site and operation of the telepharmacy system shall be limited to [~~pharmacists employed by the provider pharmacy or personnel who~~]:

(I) **pharmacists employed by the provider pharmacy;**

(II) [~~are~~] licensed healthcare providers**, if the remote site is a remote healthcare site; and**

(III) pharmacy technicians**;** [~~or pharmacy technician trainees;~~]

(vi) Individuals authorized by to access the remote site and operate the telepharmacy system shall:

(I) [~~(II) are~~] **be** designated in writing by the pharmacist-in-charge; and

(II) [~~(III)~~] have completed documented training concerning their duties associated with the telepharmacy pharmacy system.

(vi) [~~(v)~~] Remote sites shall have adequate security and procedures to:

(I) comply with federal and state laws and regulations; and

(II) maintain patient confidentiality.

~~[(vi) The provider pharmacy shall have procedures that specify that drugs may only be delivered to the remote site by the provider pharmacy and shall:~~

~~(I) be shipped in a sealed container with a list of drugs delivered;~~

~~(II) signed for on receipt by an employee of the healthcare facility;~~

~~(III) be quarantined in a locked area, if personnel designated to receive the drugs by the pharmacist-in-charge is not available; and~~

~~(IV) be checked by personnel designated by the pharmacist-in-charge to verify that drugs sent by the provider pharmacy were actually received. The designated person who checks the order shall document the verification by signing and dating the list of drugs delivered.~~]

(D) Prescription dispensing and delivery.

~~[(i) Drugs shall only be dispensed at the remote site through a telepharmacy system after receipt of an original prescription drug order by a pharmacist at the provider pharmacy in the manner authorized by §291.34(b) of this title.~~

~~(ii) Drugs may be dispensed by the provider pharmacy through a telepharmacy system at a remote site only in unit-of-use containers that are:~~

~~(I) prepackaged in suitable containers at the provider pharmacy and appropriately labeled as specified in §291.33(c)(6) of this title; or~~

~~(II) in original manufacturer's containers.~~]

~~[(iii) The following duties shall be performed only by a pharmacist at the provider pharmacy:~~

~~(I) receiving an oral prescription drug order;~~

~~(II) interpret the prescription drug order;~~

~~(III) verify the accuracy of prescription data entry;~~

~~(IV) select the drug product;~~

~~(V) interpret the patient's medication record and conduct a drug regimen review as specified in clause (iv) of this subparagraph;~~

~~(VI) authorize the telepharmacy system to print a prescription label at the remote site as specified in clause (v) of this subparagraph;~~

~~(VII) perform the final check of the dispensed prescription as specified in clause (vi) of this subparagraph to ensure that the prescription drug order has been dispensed accurately as prescribed;~~

~~(VIII) counsel the patient as specified clause (vii) of this subparagraph.~~]

(i) ~~[(iv)]~~ A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified in §291.33(c) of this title prior to delivery of the dispensed prescription to the patient or patient's agent.

(ii) ~~[(v)]~~ The dispensed prescription shall be labeled at the remote site with the information specified in §291.33(c) of this title [~~except that:~~

~~(I) the label shall contain both the name, address, and phone number of the provider pharmacy and the name and address of the remote site; and~~

~~(II) the unique identification number of the prescription on the label shall in some manner identify the remote site which dispensed the prescription using a telepharmacy system~~].

(ii) ~~[(vi)]~~ A pharmacist at the provider pharmacy shall perform the final check of the dispensed prescription before delivery to the patient to ensure that the prescription has been dispensed accurately as prescribed. This final check shall be accomplished through a visual check using electronic methods.

(iii) ~~[(vii)]~~ A pharmacist at the provider pharmacy shall counsel the patient or patient's agent as specified in §291.33(c) of this title. This counseling may be performed using electronic methods. Non-pharmacist personnel may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(iv) ~~[(viii)]~~ If the remote site has direct access to the provider pharmacy's data processing system, only a pharmacist **or**[~~,~~] pharmacy technician[~~, or pharmacy technician trainee~~] may enter prescription information into the data processing system. [~~The original prescription shall be sent to the provider pharmacy and a pharmacist shall verify the accuracy of the data entry.~~]

(v) ~~[(ix)]~~ Drugs which require reconstitution through the addition of a specified amount of water may be dispensed by the remote site only if a pharmacy technician, pharmacy technician trainee, or licensed healthcare provider reconstitutes the product.

(vi) A telepharmacy system located at a remote dispensing site may not dispense a schedule II controlled substance.

(E) Quality assurance program. A pharmacy that provides **remote** pharmacy services through a telepharmacy system at a remote site shall operate according to a written program for quality assurance of the telepharmacy system which:

(i) requires continuous supervision of the telepharmacy system at all times the site is open to provide **remote** pharmacy services; and

(ii) establishes mechanisms and procedures to routinely test the operation of the telepharmacy system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(F) Policies and procedures.

(i) A pharmacy that provides pharmacy services through a telepharmacy system at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) a current list of the name and address of the pharmacist-in-charge and personnel designated by the pharmacist-in-charge to have:

(-a-) have access to the area where drugs are stored at the remote site; and

(-b-) operate the telepharmacy system;

(II) duties which may only be performed by a pharmacist;

(III) **if the remote site is located at a remote healthcare site,** a copy of the written contact or agreement between the provider pharmacy and the healthcare facility which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations;

(IV) date of last review/revision of policy and procedure manual; and

(V) policies and procedures for:

(-a-) security;

(-b-) operation of the telepharmacy system;

(-c-) sanitation;

(-d-) storage of drugs;

(-e-) dispensing;

(-f-) supervision;

(-g-) drug and/or device procurement;

(-h-) receiving of drugs and/or devices;

(-i-) delivery of drugs and/or devices; and

(-j-) recordkeeping

(ii) A pharmacy that provides **remote** pharmacy services through a telepharmacy system at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services through a telepharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of a pharmacist to electronically supervise the telepharmacy system and the dispensing of prescription drugs at the remote site. The written plan for recovery shall include:

(I) a statement that prescription drugs shall not be dispensed at the remote site, if a **pharmacist** [~~pharmacists~~] is not able to electronically supervise the telepharmacy system and the dispensing of prescription drugs;

(II) procedures for response when a telepharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(6) Additional operational standards for remote dispensing sites.

(A) A pharmacist employed by a provider pharmacy shall make at least monthly on-site visits to a remote site. The remote site shall maintain documentation of the visit.

(B) A pharmacist employed by a provider pharmacy shall be physically present at a remote dispensing site when the pharmacist is providing services requiring the physical presence of the pharmacist, including immunizations.

(C) A remote dispensing site shall be staffed by an on-site pharmacy technician who is under the continuous supervision of a pharmacist employed by the provider pharmacy.

(D) All pharmacy technicians at a remote dispensing site shall be counted for the purpose of establishing the pharmacist-pharmacy technician ratio of the provider pharmacy which, notwithstanding Section 568.006 of the Act, may not exceed three pharmacy technicians for each pharmacist providing supervision.

(E) A pharmacy technician working at a remote dispensing site must:

(i) have worked at least one year at a retail pharmacy during the three years preceding the date the pharmacy technician begins working at the remote dispensing site; and

(ii) have completed a training program on the proper use of a telepharmacy system.

(H) A pharmacy technician at a remote dispensing site may not perform sterile or nonsterile compounding. However, a pharmacy technician may prepare commercially available medications for dispensing, including the reconstitution of orally administered powder antibiotics.

(7) ~~[(5)]~~ Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(ii) The provider pharmacy shall maintain original prescription drug orders for medications dispensed from a remote site using a telepharmacy system in the manner required by §291.34(b) of this title.

(iii) If prescription drug records are maintained in a data processing system, the system shall have a workable (electronic) data retention system which can produce a separate audit trail of drug usage by the provider pharmacy and by each remote site for the preceding two years as specified in §291.34(e) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Patient medication records. Patient medication records shall be created and maintained at the provider pharmacy in the manner required by §291.34(c) of this title.

(D) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs **ordered and dispensed by** [~~sent to and returned from~~] a remote site separate from the records of the provider pharmacy and from any other remote site's records;

(II) keep a perpetual inventory of **all** controlled substances [~~and other drugs required to be inventoried under §291.17 of this title,~~] that are received and dispensed or distributed from each remote site. **The perpetual inventory shall be reconciled, by a pharmacist employed by the provider pharmacy, at least monthly.**

(ii) As specified in §291.17 of this title. A provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs at the provider pharmacy.

H.B. No. 2561

AN ACT

relating to the continuation and functions of the Texas State Board of Pharmacy and the regulation of certain prescription drugs, prescription drug prescribers and dispensers, and colleges of pharmacy; authorizing a reduction in fees.

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

SECTION 1. Section 481.003(a), Health and Safety Code, is amended to read as follows:

(a) The director may adopt rules to administer and enforce this chapter, other than Sections 481.073, 481.074, 481.075, 481.076, [~~and~~] 481.0761, 481.0762, 481.0763, 481.0764, 481.0765, and 481.0766. The board may adopt rules to administer Sections 481.073, 481.074, 481.075, 481.076, [~~and~~] 481.0761, 481.0762, 481.0763, 481.0764, 481.0765, and 481.0766.

SECTION 2. Section 481.074(q), Health and Safety Code, is amended to read as follows:

(q) Each dispensing pharmacist shall send all required information, including any information required to complete the Schedule III through V prescription forms, to the board by electronic transfer or another form approved by the board not later than the next business [~~seventh~~] day after the date the

prescription is completely filled.

SECTION 3. Section 481.075(i), Health and Safety Code, is amended to read as follows:

(i) Each dispensing pharmacist shall:

(1) fill in on the official prescription form or note in the electronic prescription record each item of information given orally to the dispensing pharmacy under Subsection (h) and the date the prescription is filled, and:

(A) for a written prescription, fill in the dispensing pharmacist's signature; or

(B) for an electronic prescription, appropriately record the identity of the dispensing pharmacist in the electronic prescription record;

(2) retain with the records of the pharmacy for at least two years:

(A) the official prescription form or the electronic prescription record, as applicable; and

(B) the name or other patient identification required by Section 481.074(m) or (n); and

(3) send all required information, including any information required to complete an official prescription form or electronic prescription record, to the board by electronic transfer or another form approved by the board not later than the next business [~~seventh~~] day after the date the prescription is completely filled.

SECTION 4. Sections 481.076(a) and (d), Health and Safety Code, are amended to read as follows:

(a) The board may not permit any person to have access to information submitted to the board under Section 481.074(q) or 481.075 except:

(1) [~~an investigator for~~] the board, the Texas Medical Board, the Texas State Board of Podiatric Medical Examiners, the State Board of Dental Examiners, the State Board of Veterinary Medical Examiners, the Texas Board of Nursing, or the Texas Optometry Board for the purpose of:

(A) investigating a specific license holder; or

(B) monitoring for potentially harmful prescribing or dispensing patterns or practices under Section 481.0762;

(2) an authorized officer or member of the department or authorized employee of the board engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

(3) the department on behalf of a law enforcement or prosecutorial official engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

(4) a medical examiner conducting an investigation;

(5) provided that accessing the information is authorized under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and regulations

adopted under that Act:

(A) a pharmacist or a pharmacy technician, as defined by Section 551.003, Occupations Code, acting at the direction of a pharmacist; or

(B) a practitioner who:

(i) is a physician, dentist, veterinarian, podiatrist, optometrist, or advanced practice nurse or is a physician assistant described by Section 481.002(39)(D) or an employee or other agent of a practitioner acting at the direction of a practitioner; and

(ii) is inquiring about a recent Schedule II, III, IV, or V prescription history of a particular patient of the practitioner[~~, provided that the person accessing the information is authorized to do so under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and rules adopted under that Act~~];

(6) a pharmacist or practitioner who is inquiring about the person's own dispensing or prescribing activity; or

(7) one or more states or an association of states with which the board has an interoperability agreement, as provided by Subsection (j).

(d) Information submitted to the board under this section may be used only for:

(1) the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state

or another state;

(2) investigatory, [~~or~~] evidentiary, or monitoring purposes in connection with the functions of an agency listed in Subsection (a)(1);

(3) the prescribing and dispensing of controlled substances by a person listed in Subsection (a)(5); or

(4) [~~(3)~~] dissemination by the board to the public in the form of a statistical tabulation or report if all information reasonably likely to reveal the identity of each patient, practitioner, or other person who is a subject of the information has been removed.

SECTION 5. Section 481.0761, Health and Safety Code, is amended by adding Subsections (h), (i), (j), and (k) to read as follows:

(h) The board, in consultation with the department and the regulatory agencies listed in Section 481.076(a)(1), shall identify prescribing practices that may be potentially harmful and patient prescription patterns that may suggest drug diversion or drug abuse. The board shall determine the conduct that constitutes a potentially harmful prescribing pattern or practice and develop indicators for levels of prescriber or patient activity that suggest a potentially harmful prescribing pattern or practice may be occurring or drug diversion or drug abuse may be occurring.

(i) The board, based on the indicators developed under Subsection (h), may send an electronic notification to a dispenser

or prescriber if the information submitted under Section 481.074(q) or 481.075 indicates a potentially harmful prescribing pattern or practice may be occurring or drug diversion or drug abuse may be occurring.

(j) The board by rule may develop guidelines identifying behavior suggesting a patient is obtaining controlled substances that indicate drug diversion or drug abuse is occurring. A pharmacist who observes behavior described by this subsection by a person who is to receive a controlled substance shall access the information under Section 481.076(a)(5) regarding the patient for whom the substance is to be dispensed.

(k) The board by rule may develop guidelines identifying patterns that may indicate that a particular patient to whom a controlled substance is prescribed or dispensed is engaging in drug abuse or drug diversion. These guidelines may be based on the frequency of prescriptions issued to and filled by the patient, the types of controlled substances prescribed, and the number of prescribers who prescribe controlled substances to the patient. The board may, based on the guidelines developed under this subsection, send a prescriber or dispenser an electronic notification if there is reason to believe that a particular patient is engaging in drug abuse or drug diversion.

SECTION 6. Subchapter C, Chapter 481, Health and Safety Code, is amended by adding Sections 481.0762, 481.0763, 481.0764, 481.0765, and 481.0766 to read as follows:

Sec. 481.0762. MONITORING BY REGULATORY AGENCY. (a) Each regulatory agency that issues a license, certification, or registration to a prescriber shall promulgate specific guidelines for prescribers regulated by that agency for the responsible prescribing of opioids, benzodiazepines, barbiturates, or carisoprodol.

(b) A regulatory agency that issues a license, certification, or registration to a prescriber shall periodically access the information submitted to the board under Sections 481.074(q) and 481.075 to determine whether a prescriber is engaging in potentially harmful prescribing patterns or practices.

(c) If the board sends a prescriber an electronic notification authorized under Section 481.0761(i), the board shall immediately send an electronic notification to the appropriate regulatory agency.

(d) In determining whether a potentially harmful prescribing pattern or practice is occurring, the appropriate regulatory agency, at a minimum, shall consider:

(1) the number of times a prescriber prescribes opioids, benzodiazepines, barbiturates, or carisoprodol; and

(2) for prescriptions described by Subdivision (1), patterns of prescribing combinations of those drugs and other dangerous combinations of drugs identified by the board.

(e) If, during a periodic check under this section, the regulatory agency finds evidence that a prescriber may be engaging

in potentially harmful prescribing patterns or practices, the regulatory agency may notify that prescriber.

(f) A regulatory agency may open a complaint against a prescriber if the agency finds evidence during a periodic check under this section that the prescriber is engaging in conduct that violates this subchapter or any other statute or rule.

Sec. 481.0763. REGISTRATION BY REGULATORY AGENCY. A regulatory agency that issues a license, certification, or registration to a prescriber or dispenser shall provide the board with any necessary information for each prescriber or dispenser, including contact information for the notifications described by Sections 481.0761(i) and (k), to register the prescriber or dispenser with the system by which the prescriber or dispenser receives information as authorized under Section 481.076(a)(5).

Sec. 481.0764. DUTIES OF PRESCRIBERS, PHARMACISTS, AND RELATED HEALTH CARE PRACTITIONERS. (a) A person authorized to receive information under Section 481.076(a)(5), other than a veterinarian, shall access that information with respect to the patient before prescribing or dispensing opioids, benzodiazepines, barbiturates, or carisoprodol.

(b) A person authorized to receive information under Section 481.076(a)(5) may access that information with respect to the patient before prescribing or dispensing any controlled substance.

(c) A veterinarian authorized to access information under Subsection (b) regarding a controlled substance may access the

information for prescriptions dispensed only for the animals of an owner and may not consider the personal prescription history of the owner.

(d) A violation of Subsection (a) is grounds for disciplinary action by the regulatory agency that issued a license, certification, or registration to the person who committed the violation.

(e) This section does not grant a person the authority to issue prescriptions for or dispense controlled substances.

Sec. 481.0765. EXCEPTIONS. (a) A prescriber is not subject to the requirements of Section 481.0764(a) if:

(1) the patient has been diagnosed with cancer or the patient is receiving hospice care; and

(2) the prescriber clearly notes in the prescription record that the patient was diagnosed with cancer or is receiving hospice care, as applicable.

(b) A dispenser is not subject to the requirements of Section 481.0764(a) if it is clearly noted in the prescription record that the patient has been diagnosed with cancer or is receiving hospice care.

(c) A prescriber or dispenser is not subject to the requirements of Section 481.0764(a) and a dispenser is not subject to a rule adopted under Section 481.0761(j) if the prescriber or dispenser makes a good faith attempt to comply but is unable to access the information under Section 481.076(a)(5) because of

circumstances outside the control of the prescriber or dispenser.

Sec. 481.0766. REPORTS OF WHOLESALE DISTRIBUTORS. (a) A wholesale distributor shall report to the board the information that the distributor is required to report to the Automation of Reports and Consolidated Orders System (ARCOS) of the Federal Drug Enforcement Administration for the distribution of a controlled substance by the distributor to a person in this state. The distributor shall report the information to the board in the same format and with the same frequency as the information is reported to ARCOS.

(b) Information reported to the board under Subsection (a) is confidential and not subject to disclosure under Chapter 552, Government Code.

SECTION 7. (a) Subtitle A, Title 6, Health and Safety Code, is amended by adding Chapter 442 to read as follows:

CHAPTER 442. DONATION OF PRESCRIPTION DRUGS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 442.001. DEFINITIONS. In this chapter:

(1) "Donor" means an individual who donates unused prescription drugs under this chapter to a participating provider.

(2) "Health care facility" means a facility that provides health care services to patients and maintains a pharmacy in the facility. The term includes the following facilities if a pharmacy is maintained in the facility:

(A) a general or special hospital as defined by

Chapter 241;

(B) an ambulatory surgical center licensed under Chapter 243; and

(C) an institution licensed under Chapter 242.

(3) "Health care professional" means an individual licensed, certified, or otherwise authorized to administer health care and prescribe prescription drugs, for profit or otherwise, in the ordinary course of business or professional practice. The term does not include a health care facility.

(4) "Participating provider" means a health care facility or pharmacy, or a pharmacist who is an employee of the facility or pharmacy, that elects to participate in the collection and redistribution of donated prescription drugs under this chapter.

(5) "Pharmacist" means a person licensed under Chapter 558, Occupations Code.

(6) "Pharmacy" means an entity licensed under Chapter 560, Occupations Code.

(7) "Prescription drug" has the meaning assigned by Section 551.003, Occupations Code.

(8) "Recipient" means an individual who voluntarily receives donated prescription drugs under this chapter.

(9) "Tamper-evident" means packaging that allows for detection of unauthorized access to a prescription drug.

Sec. 442.002. RULEMAKING AUTHORITY. The executive

commissioner may adopt rules to implement this chapter.

Sec. 442.003. CONSTRUCTION WITH OTHER LAW. This chapter does not limit the authority of this state or a political subdivision of this state to regulate or prohibit a prescription drug.

SUBCHAPTER B. DONATION AND REDISTRIBUTION OF UNUSED PRESCRIPTION DRUGS

Sec. 442.051. DONATION AND REDISTRIBUTION OF PRESCRIPTION DRUGS. (a) A donor may donate unused prescription drugs to a participating provider in accordance with this chapter and rules adopted under this chapter.

(b) A participating provider may dispense donated prescription drugs to a recipient in accordance with this chapter and rules adopted under this chapter.

Sec. 442.052. STANDARDS FOR DONATION AND REDISTRIBUTION. (a) The executive commissioner by rule shall adopt standards and procedures for:

(1) accepting, storing, labeling, and dispensing donated prescription drugs; and

(2) inspecting donated prescription drugs to determine whether the drugs are adulterated and whether the drugs are safe and suitable for redistribution.

(b) In adopting standards and procedures under this section, the executive commissioner shall ensure that the donation and redistribution process is consistent with public health and safety standards.

Sec. 442.053. REQUIREMENTS FOR DONATED PRESCRIPTION DRUGS. (a) A donated prescription drug may be accepted or dispensed under this chapter only if the drug is in its original, unopened, sealed, and tamper-evident unit-dose packaging. A drug packaged in single unit doses may be accepted and dispensed if the outside packaging is opened but the single unit-dose packaging is unopened.

(b) A donated prescription drug may not be accepted or dispensed under this chapter if:

(1) the drug is a controlled substance;

(2) the drug is adulterated or misbranded;

(3) the drug is not stored in compliance with the drug's product label; or

(4) the United States Food and Drug Administration requires the drug to have a risk evaluation or mitigation strategy.

(c) A participating provider shall comply with all applicable provisions of state and federal law relating to the inspection, storage, labeling, and dispensing of prescription drugs.

Sec. 442.054. DONATION PROCESS. (a) Before being dispensed to a recipient, a prescription drug donated under this chapter must be inspected by the participating provider in accordance with federal law, laws of this state, and department rule to determine whether the drug is adulterated or misbranded and whether the drug has been stored in compliance with the requirements of the product label.

(b) A donated prescription drug dispensed to a recipient

under this chapter must be prescribed by a health care professional for use by the recipient.

(c) A participating provider may charge a handling fee not to exceed $20 to a recipient to cover the costs of inspecting, storing, labeling, and dispensing the donated prescription drug. A participating provider may not resell a prescription drug donated under this chapter. A donor may not sell a prescription drug to a participating provider.

(d) A participating provider may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated prescription drugs dispensed to a recipient under this chapter. A public or private third-party payor is not required to provide reimbursement for donated drugs dispensed to a recipient under this chapter.

Sec. 442.055. DONOR FORM. Before donating a prescription drug under this chapter, a donor shall sign a form prescribed by the department stating that:

(1) the donor is the owner of the donated prescription drug;

(2) the donated prescription drug has been properly stored and the container has not been opened or tampered with;

(3) the donated prescription drug has not been adulterated or misbranded; and

(4) the donor is voluntarily donating the prescription drug.

Sec. 442.056. RECIPIENT FORM. Before accepting a donated prescription drug under this chapter, a recipient shall sign a form prescribed by the department stating that:

(1) the recipient acknowledges that the donor is not a pharmacist and the donor took ordinary care of the prescription drug;

(2) the recipient acknowledges that the donor is known to the participating provider and that there is no reason to believe that the prescription drug was improperly handled or stored;

(3) by accepting the prescription drug, the recipient accepts any risk that an accidental mishandling could create; and

(4) the recipient releases the donor, participating provider, and manufacturer of the drug from liability related to the prescription drug.

Sec. 442.057. LIMITATION OF LIABILITY. (a) A donor or participating provider who acts in good faith in donating, accepting, storing, labeling, distributing, or dispensing prescription drugs under this chapter:

(1) is not criminally liable and is not subject to professional disciplinary action for those activities; and

(2) is not civilly liable for damages for bodily injury, death, or property damage that arises from those activities unless the injury, death, or damage arises from the donor or participating provider's recklessness or intentional conduct.

(b) A manufacturer of a prescription drug that donates a drug under this chapter is not, in the absence of bad faith, criminally or civilly liable for bodily injury, death, or property damage arising from the donation, acceptance, or dispensing of the drug, including the manufacturer's failure to communicate to a donor or other person:

(1) product or consumer information about the donated prescription drug; or

(2) the expiration date of the donated prescription drug.

Sec. 442.058. DATABASE OF PARTICIPATING PROVIDERS. The department shall establish and maintain an electronic database that lists each participating provider. The department shall post the database on its Internet website.

(b) If before implementing any provision of this section a state agency determines that a waiver or authorization from a federal agency is necessary for implementation of that provision, the agency affected by the provision shall request the waiver or authorization and may delay implementing that provision until the waiver or authorization is granted.

SECTION 8. Section 551.005, Occupations Code, is amended to read as follows:

Sec. 551.005. APPLICATION OF SUNSET ACT. The Texas State Board of Pharmacy is subject to Chapter 325, Government Code (Texas Sunset Act). Unless continued in existence as provided by that

chapter, the board is abolished and this subtitle expires September 1, 2029 [~~2017~~].

SECTION 9. Chapter 551, Occupations Code, is amended by adding Sections 551.006 and 551.008 to read as follows:

Sec. 551.006. EXCLUSIVE AUTHORITY. Notwithstanding any other law, a pharmacist has the exclusive authority to determine whether or not to dispense a drug.

Sec. 551.008. PROHIBITION ON RULE VIOLATING SINCERELY HELD RELIGIOUS BELIEF. (a) All rules, regulations, or policies adopted by the board may not violate Chapter 110, Civil Practice and Remedies Code.

(b) A person may assert a violation of Subsection (a) as an affirmative defense in an administrative hearing or as a claim or defense in a judicial proceeding under Chapter 37, Civil Practice and Remedies Code.

SECTION 10. Section 552.006, Occupations Code, is amended by amending Subsection (b) and adding Subsection (d) to read as follows:

(b) The training program must provide the person with information regarding:

(1) the law governing the board's operations;

(2) [~~this subtitle and~~] the programs, functions, rules, and budget of the board;

(3) the scope of and limitations on the rulemaking authority of the board;

(4) the types of board rules, interpretations, and enforcement actions that may implicate federal antitrust law by limiting competition or impacting prices charged by persons engaged in a profession or business the board regulates, including rules, interpretations, and enforcement actions that:

(A) regulate the scope of practice of persons in a profession or business the board regulates;

(B) restrict advertising by persons in a profession or business the board regulates;

(C) affect the price of goods or services provided by persons in a profession or business the board regulates; and

(D) restrict participation in a profession or business the board regulates;

(5) [~~(2)~~] the results of the most recent formal audit of the board;

(6) [~~(3)~~] the requirements of:

(A) laws relating to open meetings, public information, administrative procedure, and disclosing conflicts of interest; and

(B) other laws applicable to members of the board in performing their duties; and

(7) [~~(4)~~] any applicable ethics policies adopted by the board or the Texas Ethics Commission.

(d) The executive director shall create a training manual that includes the information required by Subsection (b). The

executive director shall distribute a copy of the training manual annually to each board member. On receipt of the training manual, each board member shall sign and submit to the executive director a statement acknowledging receipt of the training manual. The board shall publish a copy of each signed statement on the board's Internet website.

SECTION 11. Section 553.003(b), Occupations Code, is amended to read as follows:

(b) The executive director is a full-time employee of the board and shall:

(1) serve as secretary to the board; [~~and~~]

(2) perform the regular administrative functions of the board and any other duty as the board directs; and

(3) under the direction of the board, perform the duties required by this subtitle or designated by the board.

SECTION 12. Subchapter A, Chapter 554, Occupations Code, is amended by adding Section 554.0011 to read as follows:

Sec. 554.0011. USE OF ALTERNATIVE RULEMAKING AND DISPUTE RESOLUTION. (a) The board shall develop a policy to encourage the use of:

(1) negotiated rulemaking procedures under Chapter 2008, Government Code, for the adoption of board rules; and

(2) appropriate alternative dispute resolution procedures under Chapter 2009, Government Code, to assist in the resolution of internal and external disputes under the board's

jurisdiction.

(b) The board's procedures relating to alternative dispute resolution must conform, to the extent possible, to any model guidelines issued by the State Office of Administrative Hearings for the use of alternative dispute resolution by state agencies.

(c) The board shall:

(1) coordinate the implementation of the policy adopted under Subsection (a);

(2) provide training as needed to implement the procedures for negotiated rulemaking or alternative dispute resolution; and

(3) collect data concerning the effectiveness of those procedures.

SECTION 13. Section 554.051(a-1), Occupations Code, is amended to read as follows:

(a-1) The board may adopt rules to administer Sections 481.073, 481.074, 481.075, 481.076, [~~and~~] 481.0761, 481.0762, 481.0763, 481.0764, 481.0765, and 481.0766, Health and Safety Code.

SECTION 14. Section 558.051(a), Occupations Code, is amended to read as follows:

(a) To qualify for a license to practice pharmacy, an applicant for licensing by examination must submit to the board:

(1) a license fee set by the board; and

(2) a completed application on a form prescribed by the board with satisfactory sworn evidence that the applicant:

(A) is at least 18 years of age;

(B) [~~is of good moral character;~~

[~~(C)~~] has completed a minimum of a 1,000-hour internship or other program that has been approved by the board or has demonstrated, to the board's satisfaction, experience in the practice of pharmacy that meets or exceeds the board's minimum internship requirements;

(C) [~~(D)~~] has graduated and received a professional practice degree, as defined by board rule, from an accredited pharmacy degree program approved by the board;

(D) [~~(E)~~] has passed the examination required by the board; and

(E) [~~(F)~~] has not had a pharmacist license granted by another state restricted, suspended, revoked, or surrendered, for any reason.

SECTION 15. Section 558.101(a), Occupations Code, is amended to read as follows:

(a) To qualify for a license to practice pharmacy, an applicant for licensing by reciprocity must:

(1) submit to the board:

(A) a reciprocity fee set by the board; and

(B) a completed application in the form prescribed by the board, given under oath;

(2) [~~be of good moral character;~~

[~~(3)~~] have graduated and received a professional

practice degree, as defined by board rule, from an accredited pharmacy degree program approved by the board;

(3) [~~(4)~~] have presented to the board:

(A) proof of current or initial licensing by examination; and

(B) proof that the current license and any other license granted to the applicant by another state has not been restricted, suspended, revoked, or surrendered for any reason; and

(4) [~~(5)~~] pass the Texas Pharmacy Jurisprudence examination.

SECTION 16. Section 559.003, Occupations Code, is amended by adding Subsection (f) to read as follows:

(f) The board may refuse to renew a license to practice pharmacy for a license holder who is in violation of a board order.

SECTION 17. Section 562.110, Occupations Code, is amended by amending Subsections (a), (b), (d), (e), and (f) and adding Subsections (g), (h), and (i) to read as follows:

(a) In this section:

(1) "Provider pharmacy" means a Class A pharmacy that provides pharmacy services through a telepharmacy system at a remote dispensing site.

(2) "Remote dispensing site" means a location licensed as a telepharmacy that is authorized by a provider pharmacy through a telepharmacy system to store and dispense prescription drugs and devices, including dangerous drugs and controlled substances.

(3) "Telepharmacy[~~, "telepharmacy~~] system" means a system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method, including the use of the following types of technology:

(A) [~~(1)~~] audio and video;

(B) [~~(2)~~] still image capture; and

(C) [~~(3)~~] store and forward.

(b) A Class A or Class C pharmacy located in this state may provide pharmacy services, including the dispensing of drugs, through a telepharmacy system at locations separate from [~~in a facility that is not at the same location as~~] the Class A or Class C pharmacy.

(d) A telepharmacy system may be located only at:

(1) a health care facility in this state that is regulated by this state or the United States; or

(2) a remote dispensing site.

(e) The board shall adopt rules regarding the use of a telepharmacy system under this section, including:

(1) the types of health care facilities at which a telepharmacy system may be located under Subsection (d)(1), which must include the following facilities:

(A) a clinic designated as a rural health clinic regulated under 42 U.S.C. Section 1395x(aa)[~~, as amended~~]; and

(B) a health center as defined by 42 U.S.C. Section

254b[~~, as amended~~];

(2) the locations eligible to be licensed as remote dispensing sites, which must include locations in medically underserved areas, areas with a medically underserved population, and health professional shortage areas determined by the United States Department of Health and Human Services;

(3) licensing and operating requirements for remote dispensing sites, including:

(A) a requirement that a remote dispensing site license identify the provider pharmacy that will provide pharmacy services at the remote dispensing site;

(B) a requirement that a provider pharmacy be allowed to provide pharmacy services at not more than two remote dispensing sites;

(C) a requirement that a pharmacist employed by a provider pharmacy make at least monthly on-site visits to a remote dispensing site or more frequent visits if specified by board rule;

(D) a requirement that each month the perpetual inventory of controlled substances at the remote dispensing site be reconciled to the on-hand count of those controlled substances at the site by a pharmacist employed by the provider pharmacy;

(E) a requirement that a pharmacist employed by a provider pharmacy be physically present at a remote dispensing site when the pharmacist is providing services requiring the physical presence of the pharmacist, including immunizations;

(F) a requirement that a remote dispensing site be staffed by an on-site pharmacy technician who is under the continuous supervision of a pharmacist employed by the provider pharmacy;

(G) a requirement that all pharmacy technicians at a remote dispensing site be counted for the purpose of establishing the pharmacist-pharmacy technician ratio of the provider pharmacy, which, notwithstanding Section 568.006, may not exceed three pharmacy technicians for each pharmacist providing supervision;

(H) a requirement that, before working at a remote dispensing site, a pharmacy technician must:

(i) have worked at least one year at a retail pharmacy during the three years preceding the date the pharmacy technician begins working at the remote dispensing site; and

(ii) have completed a board-approved training program on the proper use of a telepharmacy system;

(I) a requirement that pharmacy technicians at a remote dispensing site may not perform extemporaneous sterile or nonsterile compounding but may prepare commercially available medications for dispensing, including the reconstitution of orally administered powder antibiotics; and

(J) any additional training or practice experience requirements for pharmacy technicians at a remote dispensing site;

(4) the areas that qualify under Subsection (f);

(5) [~~(3)~~] recordkeeping requirements; and

(6) [~~(4)~~] security requirements.

(f) A telepharmacy system located at a health care facility under Subsection (d)(1) may not be located in a community in which a Class A or Class C pharmacy is located as determined by board rule. If a Class A or Class C pharmacy is established in a community in which a telepharmacy system has been located under this section, the telepharmacy system may continue to operate in that community.

(g) A telepharmacy system located at a remote dispensing site under Subsection (d)(2) may not dispense a controlled substance listed in Schedule II as established by the commissioner of state health services under Chapter 481, Health and Safety Code, and may not be located within 22 miles by road of a Class A pharmacy.

(h) If a Class A pharmacy is established within 22 miles by road of a remote dispensing site that is currently operating, the remote dispensing site may continue to operate at that location.

(i) The board by rule shall require and develop a process for a remote dispensing site to apply for classification as a Class A pharmacy if the average number of prescriptions dispensed each day the remote dispensing site is open for business is more than 125, as calculated each calendar year.

SECTION 18. Section 568.002(c), Occupations Code, is amended to read as follows:

(c) An applicant for registration as a pharmacy technician or a pharmacy technician trainee must[~~:~~

[~~(1) be of good moral character; and~~

[~~(2)~~] submit an application on a form prescribed by the board.

SECTION 19. Section 568.004, Occupations Code, is amended to read as follows:

Sec. 568.004. RENEWAL OF REGISTRATION. (a) The board may adopt a system in which the registrations of pharmacy technicians and pharmacy technician trainees expire on various dates during the year.

(b) To renew a pharmacy technician registration, the registrant must, before the expiration date of the registration:

(1) pay a renewal fee as determined by the board under Section 568.005; and

(2) comply with the continuing education requirements prescribed by the board in accordance with Section 568.0045.

(c) A person whose pharmacy technician registration has been expired for 90 days or less may renew the expired registration by paying to the board a renewal fee that is equal to one and one-half times the normally required renewal fee for the registration.

(d) A person whose pharmacy technician registration has been expired for more than 90 days but less than one year may renew the expired registration by paying to the board a renewal fee that is equal to two times the normally required renewal fee for the registration.

(e) A person whose pharmacy technician registration has been

expired for one year or more may not renew the registration. The person may register by complying with the requirements and procedures for initially registering, including the examination requirement.

(f) The board may refuse to renew a pharmacy technician registration for a registrant who is in violation of a board order.

SECTION 20. Chapter 568, Occupations Code, is amended by adding Section 568.0045 to read as follows:

Sec. 568.0045. RULES RELATING TO CONTINUING EDUCATION. The board shall adopt rules relating to the continuing education required for pharmacy technicians. The rules must include requirements for:

(1) the number of hours of continuing education;

(2) the methods for meeting the continuing education requirements;

(3) the approval of continuing education programs;

(4) reporting completion of continuing education;

(5) records of completion of continuing education; and

(6) board audits to ensure compliance with the continuing education requirements.

SECTION 21. Section 89.051(b), Education Code, is amended to read as follows:

(b) The college shall be known as The Texas A&M University System Health Science Center Irma Lerma Rangel College of Pharmacy, and the primary building in which the school is operated shall be

located in Kleberg County and must include "Irma Rangel" in its official name.

SECTION 22. (a) A joint interim committee is created to conduct an interim study on the monitoring of the prescribing and dispensing of controlled substances in this state.

(b) The joint interim committee shall be composed of three senators appointed by the lieutenant governor and three members of the house of representatives appointed by the speaker of the house of representatives.

(c) The lieutenant governor and speaker of the house of representatives shall each designate a co-chair from among the joint interim committee members.

(d) The joint interim committee shall convene at the joint call of the co-chairs.

(e) The joint interim committee has all other powers and duties provided to a special or select committee by the rules of the senate and house of representatives, by Subchapter B, Chapter 301, Government Code, and by policies of the senate and house committees on administration.

(f) The interim study conducted by the joint interim committee must:

(1) include the number of prescribers and dispensers registered to receive information electronically under Section 481.076, Health and Safety Code, as amended by this Act;

(2) evaluate the accessing of information under Section

481.076, Health and Safety Code, as amended by this Act, by regulatory agencies to monitor persons issued a license, certification, or registration by those agencies;

(3) address any complaints, technical difficulties, or other issues with electronically accessing and receiving information under Section 481.076, Health and Safety Code, as amended by this Act;

(4) examine controlled substance prescribing and dispensing trends that may be affected by the passage and implementation of this Act;

(5) evaluate the use and effectiveness of electronic notifications sent to prescribers and dispensers under Sections 481.0761(i) and (k), Health and Safety Code, as added by this Act;

(6) evaluate the use and effectiveness of identifying geographic anomalies in comparing delivery and dispensing data;

(7) evaluate the integration of any new data elements required to be reported under this Act;

(8) evaluate the existence and scope of diversion of controlled substances by animal owners to whom the substances are dispensed by veterinarians;

(9) explore the best methods for preventing the diversion of controlled substances by animal owners; and

(10) determine how any future reporting by dispensing veterinarians might best be tailored to fit the practice of veterinary medicine.

(g) The committee shall solicit feedback from regulatory agencies, prescribers, dispensers, and patients affected by the passage of this Act.

(h) The committee shall submit a report to the legislature on the results of the interim study, including any legislative recommendations for improvements to information access and controlled substance prescription monitoring, not later than January 1, 2019.

(i) Subject to available resources, the Texas Legislative Council shall provide legal and policy research, drafts of proposed legislation, and statistical analysis services to the joint interim committee for the purpose of the study required under this section.

(j) Notwithstanding Section 481.076, Health and Safety Code, as amended by this Act, or any other law relating to access to or disclosure of prescription drug information maintained by the Texas State Board of Pharmacy, the Texas State Board of Pharmacy shall disclose any information maintained by the board under Section 481.076, Health and Safety Code, to the Texas Legislative Council on request of the council for the purpose of assisting with the study required under this section.

(k) Not later than November 1, 2017, the lieutenant governor and speaker of the house of representatives shall appoint the members of the joint interim committee in accordance with this section.

(l) The joint interim committee created under this section is

abolished and this section expires January 2, 2019.

SECTION 23. A pharmacist is not required to comply with a rule adopted under Section 481.0761(j), Health and Safety Code, as added by this Act, before January 1, 2018.

SECTION 24. Section 481.0764(a), Health and Safety Code, as added by this Act, applies only to:

(1) a prescriber other than a veterinarian who issues a prescription for a controlled substance on or after September 1, 2019; or

(2) a person authorized by law to dispense a controlled substance other than a veterinarian who dispenses a controlled substance on or after September 1, 2019.

SECTION 25. Not later than December 1, 2017, the executive commissioner of the Health and Human Services Commission shall adopt the rules necessary for the implementation of Chapter 442, Health and Safety Code, as added by this Act.

SECTION 26. (a) Except as provided by Subsection (b) of this section, Section 552.006, Occupations Code, as amended by this Act, applies to a member of the Texas State Board of Pharmacy appointed before, on, or after the effective date of this Act.

(b) A member of the Texas State Board of Pharmacy who, before the effective date of this Act, completed the training program required by Section 552.006, Occupations Code, as that law existed before the effective date of this Act, is required to complete additional training only on subjects added by this Act to the

training program as required by Section 552.006, Occupations Code, as amended by this Act. A board member described by this subsection may not vote, deliberate, or be counted as a member in attendance at a meeting of the board held on or after December 1, 2017, until the member completes the additional training.

SECTION 27. Sections 558.051, 558.101, and 568.002, Occupations Code, as amended by this Act, apply only to an application for a license to practice pharmacy or for registration as a pharmacy technician or pharmacy technician trainee filed on or after the effective date of this Act. An application for a license or registration filed before the effective date of this Act is governed by the law in effect on the date the application was filed, and the former law is continued in effect for that purpose.

SECTION 28. Section 559.003, Occupations Code, as amended by this Act, and Sections 568.004(b), (e), and (f), Occupations Code, as added by this Act, apply only to the renewal of a license to practice pharmacy or of a pharmacy technician registration on or after the effective date of this Act. The renewal of a license or registration 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 29. The Texas State Board of Pharmacy shall adopt rules under Section 562.110, Occupations Code, as amended by this Act, not later than January 1, 2018.

SECTION 30. As soon as practicable after the effective date

of this Act, the Texas State Board of Pharmacy shall adopt rules to reduce the amount of the fees imposed by the board for the renewal of an expired pharmacy technician registration to reflect the amounts provided for by Sections 568.004(c) and (d), Occupations Code, as added by this Act. A pharmacy technician who renews an expired registration certificate on or after the effective date of this Act shall pay the amount provided for by Section 568.004(c) or (d), Occupations Code, as added by this Act, instead of the amount provided for under board rules adopted before that date.

SECTION 31. This Act takes effect September 1, 2017.

_____ _____

President of the Senate Speaker of the House

I certify that H.B. No. 2561 was passed by the House on May 2, 2017, by the following vote: Yeas 145, Nays 0, 1 present, not voting; and that the House concurred in Senate amendments to H.B. No. 2561 on May 26, 2017, by the following vote: Yeas 131, Nays 15, 1 present, not voting.

_____

Chief Clerk of the House

I certify that H.B. No. 2561 was passed by the Senate, with amendments, on May 24, 2017, by the following vote: Yeas 25, Nays 6.

_____

Secretary of the Senate

APPROVED: _____

Date

_____

Governor

AN ACT

relating to the supervision of pharmacist-interns, pharmacy technicians, and pharmacy technician trainees by a pharmacist and the provision of pharmacy services through a telepharmacy system; establishing a remote dispensing site license.

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

SECTION 1. Section 551.003, Occupations Code, is amended by adding Subdivision (15-a) to read as follows:

(15-a) "Direct supervision" means supervision by a pharmacist who directs the activities of a pharmacist-intern, pharmacy technician, or pharmacy technician trainee to a sufficient degree to ensure the activities are performed accurately, safely, and without risk of harm to patients, as specified by board rule.

SECTION 2. Section 554.053(a), Occupations Code, is amended to read as follows:

(a) The board shall establish rules for the use and the duties of a pharmacy technician and pharmacy technician trainee employed by [~~in~~] a pharmacy licensed by the board. A pharmacy technician and pharmacy technician trainee shall be responsible to and must be directly supervised by a pharmacist.

SECTION 3. Section 562.110, Occupations Code, is amended by amending Subsections (a), (b), (d), (e), and (f) and adding Subsections (g), (h), (i), (j), and (k) to read as follows:

(a) In this section:

(1) "Provider pharmacy" means a Class A pharmacy that provides pharmacy services through a telepharmacy system at a remote dispensing site.

(2) "Remote dispensing site" means a location licensed as a telepharmacy that is authorized by a provider pharmacy through a telepharmacy system to store and dispense prescription drugs and devices, including dangerous drugs and controlled substances.

(3) "Telepharmacy[~~, "telepharmacy~~] system" means a system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method, including the use of the following types of technology:

(A) [~~(1)~~] audio and video;

(B) [~~(2)~~] still image capture; and

(C) [~~(3)~~] store and forward.

(b) A Class A or Class C pharmacy located in this state may provide pharmacy services, including the dispensing of drugs, through a telepharmacy system at locations separate from [~~in a facility that is not at the same location as~~] the Class A or Class C pharmacy.

(d) A telepharmacy system may be located only at:

(1) a health care facility in this state that is regulated by this state or the United States; or

(2) a remote dispensing site.

(e) The board shall adopt rules regarding the use of a telepharmacy system under this section, including:

(1) the types of health care facilities at which a

telepharmacy system may be located under Subsection (d)(1), which must include the following facilities:

(A) a clinic designated as a rural health clinic regulated under 42 U.S.C. Section 1395x(aa)[~~, as amended~~]; and

(B) a health center as defined by 42 U.S.C. Section 254b[~~, as amended~~];

(2) the locations eligible to be licensed as remote dispensing sites, which must include locations in medically underserved areas, areas with a medically underserved population, and health professional shortage areas determined by the United States Department of Health and Human Services;

(3) licensing and operating requirements for remote dispensing sites, including:

(A) a requirement that a remote dispensing site license identify the provider pharmacy that will provide pharmacy services at the remote dispensing site;

(B) a requirement that a provider pharmacy be allowed to provide pharmacy services at not more than two remote dispensing sites;

(C) a requirement that a pharmacist employed by a provider pharmacy make at least monthly on-site visits to a remote dispensing site or more frequent visits if specified by board rule;

(D) a requirement that each month the perpetual inventory of controlled substances at the remote dispensing site be reconciled to the on-hand count of those controlled substances at the site by a pharmacist employed by the provider pharmacy;

(E) a requirement that a pharmacist employed by a

provider pharmacy be physically present at a remote dispensing site when the pharmacist is providing services requiring the physical presence of the pharmacist, including immunizations;

(F) a requirement that a remote dispensing site be staffed by an on-site pharmacy technician who is under the continuous supervision of a pharmacist employed by the provider pharmacy;

(G) a requirement that all pharmacy technicians at a remote dispensing site be counted for the purpose of establishing the pharmacist-pharmacy technician ratio of the provider pharmacy, which, notwithstanding Section 568.006, may not exceed three pharmacy technicians for each pharmacist providing supervision;

(H) a requirement that, before working at a remote dispensing site, a pharmacy technician must:

(i) have worked at least one year at a retail pharmacy during the three years preceding the date the pharmacy technician begins working at the remote dispensing site; and

(ii) have completed a board-approved training program on the proper use of a telepharmacy system;

(I) a requirement that pharmacy technicians at a remote dispensing site may not perform extemporaneous sterile or nonsterile compounding but may prepare commercially available medications for dispensing, including the reconstitution of orally administered powder antibiotics; and

(J) any additional training or practice

experience requirements for pharmacy technicians at a remote dispensing site;

(4) the areas that qualify under Subsection (f);

(5) [~~(3)~~] recordkeeping requirements; and

(6) [~~(4)~~] security requirements.

(f) A telepharmacy system located at a health care facility under Subsection (d)(1) may not be located in a community in which a Class A or Class C pharmacy is located as determined by board rule. If a Class A or Class C pharmacy is established in a community in which a telepharmacy system has been located under this section, the telepharmacy system may continue to operate in that community.

(g) A telepharmacy system located at a remote dispensing site under Subsection (d)(2) may not dispense a controlled substance listed in Schedule II as established by the commissioner of state health services under Chapter 481, Health and Safety Code.

(h) Except as provided by Subsection (j), a telepharmacy system located at a remote dispensing site under Subsection (d)(2) may not be located within 25 miles by road of a Class A pharmacy.

(i) Except as provided by Subsection (j), if a Class A pharmacy is established within 25 miles by road of a remote dispensing site that is currently operating, the remote dispensing site may continue to operate at that location.

(j) A telepharmacy system located at a remote dispensing site under Subsection (d)(2) in a county with a population of at least 13,000 but not more than 14,000 may not be located within 22 miles by road of a Class A pharmacy. If a Class A pharmacy is established within 22 miles by road of a remote dispensing site

described by this subsection that is currently operating, the remote dispensing site may continue to operate at that location.

(k) The board by rule shall require and develop a process for a remote dispensing site to apply for classification as a Class A pharmacy if the average number of prescriptions dispensed each day the remote dispensing site is open for business is more than 125, as calculated each calendar year.

SECTION 4. The Texas State Board of Pharmacy shall adopt rules under Section 562.110, Occupations Code, as amended by this Act, not later than January 1, 2018.

SECTION 5. This Act takes effect September 1, 2017.

President of the Senate

Speaker of the House

I hereby certify that S.B. No. 1633 passed the Senate on April 27, 2017, by the following vote: Yeas 31, Nays 0; May 25, 2017, Senate refused to concur in House amendments and requested appointment of Conference Committee; May 26, 2017, House granted request of the Senate; May 28, 2017, Senate adopted Conference Committee Report by the following vote: Yeas 29, Nays 1.

Secretary of the Senate

I hereby certify that S.B. No. 1633 passed the House, with amendments, on May 24, 2017, by the following vote: Yeas 132, Nays 13, three present not voting; May 26, 2017, House granted request of the Senate for appointment of Conference Committee; May 28, 2017, House adopted Conference Committee Report by the following vote: Yeas 138, Nays 6, three present not voting.

Chief Clerk of the House

Approved:

Date

Governor