

West's Tennessee Code Annotated [Currentness](#)

Title 63. Professions of the Healing Arts

↳ [Chapter 10. Pharmacy \(Refs & Annos\)](#)

↳ [Part 1. Third-Party Prescription Program Act \(Refs & Annos\)](#)

↳ [§ 63-10-101. Short title](#)

This part shall be known and may be cited as the “Third-Party Prescription Program Act.”

↳ [§ 63-10-102. Definitions](#)

As used in this part, “program” and “third-party prescription program” mean any system of providing for the reimbursement of pharmaceutical services under a contractual arrangement or agreement between a provider of such services and another party who is not the consumer of those services. Such programs may include, but not be limited to, employee benefit plans whereby a consumer receives prescription drugs or other pharmaceutical services and those services are paid for by an agent of the employer or others.

↳ [§ 63-10-103. Contracts; reimbursement terms](#)

Any agreement or contract entered into in this state between the program administrator of a third-party prescription program and a pharmacy shall include a statement of:

- (1) The method and amount of reimbursement to the pharmacy for services rendered to persons enrolled in such program;
- (2) The frequency of payment by such program administrator to the pharmacy for such services rendered; and
- (3) A method for the adjudication of complaints or the settlement of disputes between the parties.

↳ [§ 63-10-104. Cancellation of coverage](#)

(a) The administrator of a program shall notify all pharmacies enrolled in such program of any cancellation of the coverage of benefits of any group enrolled in such program at least thirty (30) days prior to the effective date of such cancellation. In those cases where the administrator of a program is not notified at least thirty (30) days prior to the effective date of such cancellation, the administrator shall notify all pharmacies enrolled in such program of the cancellation as soon as practicable after having received such notice.

(b) All persons enrolled in a program shall be notified of its cancellation, and the administrator of such

program shall make every reasonable effort to gain possession of any plan identification cards such persons may have been issued pursuant to the provisions of such program.

(c) Any person who utilizes a program identification card to obtain services from a pharmacy after having received notice of the cancellation of the person's benefits shall be liable to the program administrator of such program for all moneys paid by such program administrator for any services received pursuant to the illegal use of such identification card.

→ **§ 63-10-105. Payment; denial or withholding**

(a) No program administrator shall deny payment for services to any pharmacy that may have resulted from the fraudulent or illegal use of an identification card by any person, unless the pharmacy has been notified that the card has been cancelled or discontinued and that the program administrator has been unsuccessful in attempting to regain possession of the card.

(b) No program administrator shall withhold any payments to any pharmacy beyond the time period specified in the payment schedule provisions of the agreement, except that individual claims for payment may be returned to the pharmacy for cause, such as incomplete or illegible information, and may then be resubmitted by the pharmacy to the program administrator after the appropriate corrections have been made.

(c) No program administrator shall deny or withhold payment to any pharmacy for duplicate prescription refills or prescription refills that are dispensed early in relation to the prior day's supply dispensed, where such refills are for the purpose of replacing lost or destroyed medication or providing the patient with the quantity necessary for extended travel away from the community in which the patient resides or for any other bona fide reason that causes the patient to be without medication, when the discontinuation of the medicine would, in the pharmacist's professional judgment, place the patient at risk of harm.

→ **§ 63-10-106. Reimbursement; rates**

No agreement between a program administrator and a pharmacy shall establish reimbursement rates or procedures that result in reimbursement rates for services rendered to persons covered by the plan that are less than the usual and customary rate charged by that vendor and paid by ordinary consumers for the same or similar services. The provisions of this section do not apply to any agreements involving a pharmacy that is a member of an organized pharmacy network, such as a preferred provider organization (PPO) or a professional service administration organization (PSAO).

→ **§ 63-10-107. Repealed by 1993 Pub.Acts, c. 388, § 2, eff. May 17, 1993**

→ **§ 63-10-108. Application of program**

This part does not apply to any services rendered pursuant to the provisions of the Medical Assistance Act of 1968, compiled in title 71, chapter 5, part 1.

→ **§ 63-10-109. Price level determinations**

(a) The commissioner of health, in cooperation with the board of pharmacy, shall determine the price level of prescriptions furnished under the provisions of this part and those furnished otherwise. A determination shall also be made of the price level in other states having a program similar to that provided in this part and those that do not.

(b) The commissioner shall prepare a comparison of the price level determinations required by this section no later than January 31 of each year and shall furnish copies of such comparison to committees of the general assembly.

Part 2. Pharmacy Practice (Refs & Annos)

→ **§ 63-10-201. Short title**

Parts 2-4 of this chapter shall be known and may be cited as the “Tennessee Pharmacy Practice Act of 1996.”

→ **§ 63-10-202. Legislative findings and declaration**

The practice of pharmacy within the state is declared to be a professional practice affecting public health, safety and welfare and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in § 63-10-204, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy.

→ **§ 63-10-203. Purpose**

(a) The purpose of parts 2-5 of this chapter is to define and regulate the practice of pharmacy to protect the health, safety and welfare of the people of Tennessee.

(b) The persons engaged in the practice of pharmacy shall be pharmacists, duly recognized by the state as necessary health care providers, and shall be entrusted through parts 4-6 of this chapter with a provision of care intended to enhance patients' wellness, prevent illness and optimize outcomes.

→ **§ 63-10-204. Definitions**

As used in parts 2-5 of this chapter, unless the context otherwise requires:

- (1) “Administer” means the direct application of a drug to a patient or research subject by injection, inhalation, ingestion, topical application or by any other means;
- (2) “Board” means the Tennessee board of pharmacy;
- (3) “Certification” means a voluntary process by which a practitioner's training, experience and knowledge are identified as meeting or surpassing a standard, defined or approved by the board beyond that required for licensure or registration;
- (4) “Compounding” means the preparation, mixing, assembling, packaging or labeling of a drug or device:
 - (A) As the result of a prescription order or initiative based on the prescriber-patient-pharmacist relationship in the course of professional practice;
 - (B) In anticipation of prescription orders based on routine, regularly observed prescribing patterns;
 - (C) For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing;
 - (D) For use in a licensed prescribing practitioner's office for administration to the prescribing practitioner's patient or patients when the product is not commercially available upon receipt of an order from the prescriber;
 - (E) For use in a health care facility for administration to a patient or patients receiving treatment or services provided by that facility when the product is not commercially available upon receipt of an order from an authorized licensed medical practitioner of the facility;
 - (F) For use by emergency medical services for administration to a patient or patients receiving services from them under authorized medical control when the product is not commercially available upon receipt of an order from a licensed prescriber authorized to provide medical control; or
 - (G) For use by a licensed veterinarian for administration to their non-human patient or patients or for dispensing to non-human patients in the course of the practice of veterinary medicine upon receipt of an order from a veterinarian when the product is not commercially available.
- (5) “Continuing education” means planned, organized learning experiences and activities beyond the basic educational or preparatory program. These learning experiences and activities are designed to promote the

continuous development of skills, attitudes and knowledge necessary to maintain proficiency, provide quality service or products, be responsive to needs and keep abreast of significant change;

(6) “Continuous quality improvement program” means a system of standards and procedures to identify and evaluate quality-related events and to improve patient care;

(7) “Controlled substance” means a drug, substance or immediate precursor identified, defined or listed in title 39, chapter 17, part 4 and title 53, chapter 11;

(8) “Deliver” or “delivery” means the actual, constructive or attempted transfer from one person to another whether or not there is an agency relationship;

(9) “Device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a person duly authorized;

(10) “Dietary supplement” means a product, other than tobacco, intended to supplement the diet that bears or contains one (1) or more of the following ingredients: a vitamin, mineral, herb or other botanical, amino acid, dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any of these ingredients and any other products designated as dietary supplements by federal or state law;

(11) “Director” means the director of the health related boards;

(12) “Dispense” means preparing, packaging, compounding or labeling for delivery and actual delivery of a prescription drug, nonprescription drug or device in the course of professional practice to a patient or the patient's agent, to include a licensed health care practitioner or a health care facility providing services or treatment to the patient or patients, by or pursuant to the lawful order of a prescriber;

(13) “Distribute” means the delivery of a drug or device, other than by administering or dispensing, to persons other than the patient or the patient's agent;

(14) “Division” means the division of health related boards;

(15) “Doctor of pharmacy” means a person duly licensed by the board to engage in the practice of pharmacy. “Doctor of pharmacy” and “pharmacist” shall be used interchangeably within parts 4-6 of this chapter and, any other provision of Tennessee Code Annotated and in any rule or regulation promulgated by the state of Tennessee and its agencies;

(16) “Drug” means any of the following:

(A) Articles recognized as drugs or drug products in any official compendium or supplement thereto;

(B) Articles, other than food, intended to affect the structure or function of the body of humans or other animals;

(C) Articles, including radioactive substances, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals; or

(D) Articles intended for use as a component of any articles specified in this subdivision (16);

(17) “Executive director” means the executive director of the Tennessee board of pharmacy;

(18) “Label” means any written, printed or graphic matter on the immediate container of a drug or device;

(19) “Labeling” means the process of affixing all labels and other written, printed or graphic matter:

(A) Upon any article or any of its containers or wrappers; or

(B) Accompanying such article;

(20) “Licensure” means the process by which an agency of government grants permission to an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety and welfare will be reasonably protected;

(21) “Manufacturer” means any person, except a pharmacist compounding in the normal course of professional practice, engaged in the commercial production, preparation, propagation, conversion or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both, and includes any packaging or repackaging of a drug or the labeling or relabeling of its container and the promotion and marketing of such drugs or devices;

(22) “Medical order” means a lawful order of a prescriber for a specific patient that may or may not include a prescription order, such orders subject to rules and regulations as may be promulgated from time to time by the respective boards that license the persons who are authorized to prescribe drugs;

(23) “Medication therapy management program” means the distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication therapy management services are independent of but

can occur in conjunction with the provision of a medication product;

(24) “Nonprescription device” means a device that may be sold or dispensed without a prescription order and that is labeled and packaged in compliance with applicable state or federal law;

(25) “Nonprescription drug” means a drug that may be sold or dispensed without a prescription and that is labeled and packaged in compliance with applicable state or federal law;

(26) “Patient education” means the communication of information to the patient or caregiver by the pharmacist;

(27) “Patient profile” means a written or electronic record of individual patient information, created in a pharmacy practice, for use by a pharmacist in the provision of pharmacy patient care services, including drug use review and patient counseling requirements. The profile may include, but is not limited to, demographic information, medical history, medication and devices utilized, testing results and pharmacist comments;

(28) “Peer review committee” or “pharmacist review committee” means any committee, board, commission or other entity of any national, state or local professional association or society, including an impaired pharmacist peer review committee, a drug utilization review committee or a committee of any pharmacy benefits management organization, health care provider network, licensed health care institution or any health care organization, system or foundation, the function of which, or one of the functions of which, is to review, evaluate and improve the quality of pharmacy-related services provided by pharmacists or pharmacy auxiliary personnel, to provide intervention, support or rehabilitative referrals or services or to determine that pharmacy-related services rendered by pharmacists or pharmacy auxiliary personnel were professionally indicated or were performed in compliance with applicable quality standards, or that the cost of pharmacy-related services rendered by pharmacists or pharmacy auxiliary personnel was reasonable;

(29) “Person” means any individual, partnership, association, corporation and the state of Tennessee, its departments, agencies and employees, and the political subdivisions of Tennessee and their departments, agencies and employees, except the department of health and local health departments;

(30) “Pharmacist” means an individual health care provider licensed by the state of Tennessee, pursuant to parts 4-6 of this chapter, to practice the profession of pharmacy;

(31) “Pharmacist-in-charge” means the supervisory pharmacist who has the authority and responsibility for compliance with laws and rules pertaining to the practice of pharmacy at the practice site of the pharmacist-in-charge;

(32) “Pharmacy” means a location licensed by this state where drugs are compounded or dispensed under the supervision of a pharmacist, as defined in the rules of the board and where prescription orders are received or

processed;

(33) “Pharmacy intern” means an individual enrolled in or a graduate of a recognized school or college of pharmacy under rules established by the board who is serving a period of time of practical experience under the supervision of a pharmacist, as defined in the rules of the board;

(34) “Pharmacy technician” means an individual who is specifically trained and designated to assist pharmacists in the practice of pharmacy;

(35)(A) “Practice of pharmacy” means a patient-oriented health service profession in which pharmacists interact and consult with patients and other health care professionals to enhance patients' wellness, prevent illness and optimize outcomes. The practice involves:

- (i) Interpretation, evaluation and implementation of medical orders and prescription orders;
- (ii) Responsibility for compounding and dispensing prescription orders, including radioactive substances;
- (iii) Participation in drug, dietary supplement and device selection, storage, distribution and administration;
- (iv) Drug evaluation, utilization or regimen review;
- (v) Maintenance of patient profiles and other pharmacy records;
- (vi) Provision of patient education and counseling;
- (vii) Drug or drug-related research; and
- (viii) Those professional acts, professional decisions or professional services necessary to maintain all areas of a patient's pharmacy-related care;

(B) Nothing in this chapter authorizes a pharmacist to order laboratory tests or prescription drugs except pursuant to a medical order by the attending physician for each patient; provided, that pharmacists are authorized to conduct and assist patients with tests approved for in-home use. Except as described in this section, pharmacists shall not be authorized to order or prescribe legend drugs or order laboratory tests. Pharmacists may convey orders for laboratory tests and prescription orders where required to carry out a medical order when authorized by the attending physician for each patient;

(36) “Prescriber” means an individual authorized by law to prescribe drugs;

(37) “Prescription drug” means a drug that under federal or state law is required to be dispensed only pursuant to a prescription order or is restricted to use by prescribers and that under federal law must be labeled with either the symbol “Rx only” or the statement “Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian”;

(38) “Prescription order” means and includes any order, communicated through written, verbal or electronic means by a physician, certified physician assistant, nurse authorized pursuant to § 63-6-204, who is rendering service under the supervision, control and responsibility of a licensed physician, and who meets the requirements pursuant to § 63-7-207(14), dentist, veterinarian, optometrist authorized pursuant to § 63-8-102(12), or other allied medical practitioner, for any drug, device or treatment. Nothing in this chapter shall prohibit the verbal communication of a direct order for a prescription from a physician to a pharmacist by a registered nurse or physician assistant pursuant to § 63-6-204;

(39) “Provider” or “necessary health care provider” includes a pharmacist who provides health care services within the scope of pharmacy practice;

(40) “Quality assurance program” means a system for identifying problems in patient care that are resolved via administrative, clinical or educational actions to ensure that final products and outcomes meet applicable specifications;

(41) “Quality-related event” means the inappropriate dispensing or administration of a prescribed medication, including, but not limited to:

(A) A variation from the prescriber’s medical or prescription order, including, but not limited to:

(i) Dispensing an incorrect drug;

(ii) Dispensing an incorrect drug strength;

(iii) Dispensing an incorrect dosage form;

(iv) Dispensing the drug to the wrong patient; and

(v) Providing inadequate or incorrect packaging, labeling or directions for use; and

(B) Failure to identify, prevent, resolve and manage potential and actual drug and drug-related problems, including, but not limited to:

(i) Over-utilization and under-utilization;

- (ii) Therapeutic duplication;
- (iii) Drug-age contraindications;
- (iv) Drug-allergy contraindications;
- (v) Drug-disease contraindications;
- (vi) Drug-gender contraindications;
- (vii) Drug-drug interactions;
- (viii) Incorrect drug dosage;
- (ix) Incorrect duration of drug therapy; and
- (x) Clinical abuse or misuse;

(42) “Unprofessional conduct” means the conduct of a pharmacist, pharmacy intern or pharmacy technician that is detrimental to patients or to the profession of pharmacy; and

(43) “Wholesaler” means a person whose principal business is buying or otherwise acquiring drugs or devices for resale or distribution to persons other than consumers.

→ **§ 63-10-205. Drugs, approval**

(a)(1) Any drug dispensed by the department of health or a local health department in traditional services, including, but not limited to, family planning, maternal and child health, tuberculosis and venereal disease must be approved by the board.

(2) Such approval shall be in the form of duly promulgated rules pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(b) Where a local health department does not employ a pharmacist, inventory controls, accountability, repackaging, security, storage and distribution of such drugs shall be under the supervision of a pharmacist at the regional level, as defined by the department of health.

→ **§ 63-10-206. Nonprescription drugs or devices; dispensing; insulin; prescription orders; sales and use taxes**

(a) Any nonprescription drug or device can be sold in its original single package by any retail business unless such nonprescription drug or device is required by federal or state law to be dispensed or sold only by or under the supervision of a pharmacist.

(b) Notwithstanding subsection (a) to the contrary, any insulin preparation shall be dispensed only by or under the supervision of a pharmacist. All insulin preparations must be properly stored in an area not accessible to the general public.

(c) In order to comply with federal and state law requiring pharmacies to maintain patient profiles with a comprehensive list of medications and devices, pharmacists are authorized to execute prescription orders for nonprescription drugs and devices.

(d) Nothing in this section shall be construed as exempting nonprescription drugs and devices dispensed on a prescription order executed by a pharmacist from application of the sales and use tax provisions of title 67, chapter 6.

→ **§ 63-10-207. Dispensing without authorization; limitations**

(a) Notwithstanding any provision of law to the contrary, a pharmacist may, in good faith, dispense to a patient without proper authorization the number of dosages of a prescription drug necessary to allow such patient to secure such authorization from such patient's prescriber, not to exceed a seventy-two-hour supply, if:

(1) The patient offers satisfactory evidence to the pharmacist that the prescriber has placed the patient on a maintenance medication and that such patient is without valid refills or for some valid reason cannot obtain proper authorization; and

(2) In the judgment of the pharmacist, the health, safety and welfare of the patient would otherwise be endangered.

(b) This section shall not be construed to authorize dispensing of controlled substance medication without proper authorization.

(c) If proper authorization cannot be obtained during the seventy-two-hour period, then the pharmacist may dispense the number of dosages necessary for one (1) additional consecutive seventy-two-hour period in accordance with the requirements of this section.

→ **§ 63-10-208. Violations; classification of offense**

Any violation of parts 2-5 of this chapter, unless otherwise specified by law, shall be classified as a Class C misdemeanor.

→ **§ 63-10-209. Manufacturers, representatives and agents; distribution of drugs or sample drugs; free samples of legend drugs or controlled substances**

(a) Nothing in this chapter shall prohibit the distribution of drugs or sample drugs by a manufacturer's representatives acting in the normal and customary performance of their duties.

(b) Manufacturers or their agents may distribute free samples of prescription drugs or controlled substances to practitioners authorized by law to prescribe or dispense such drugs or to pharmacies of health care entities at the written request of a practitioner in accordance with federal law.

→ **§ 63-10-210. Out-of-state pharmacists; licensure fee**

A pharmacy that dispenses and mails a prescription into Tennessee from another state shall first pay the licensure fee required of a Tennessee pharmacy in accordance with the fees established by the board under the authority of § 63-10-308. The license fees for out-of-state pharmacies and pharmacists shall not exceed those charged to Tennessee pharmacies and pharmacists.

→ **§ 63-10-211. Pharmacists; forming consortiums for making bulk purchases of drugs or medical equipment and supplies**

It is not a violation of any state law relative to restraint of trade, antitrust or any provision of the licensing laws for pharmacists, pharmacies, wholesalers, distributors or manufacturers under § 63-10-306 for pharmacists, independently or through any pharmacist or pharmacy, to form a consortium for the purpose of making bulk purchases of drugs or other medical equipment and supplies for the purpose of resale in their pharmacies.

→ **§ 63-10-212. Disclosure of patient information; liability**

(a) Notwithstanding any requirement of state law to the contrary, a pharmacist is immune from liability to any person for disclosing patient information to a person authorized by this title to prescribe drugs or devices or to communicate a prescription order where necessary to:

(1) Fulfill the pharmacist's responsibility to carry out prospective drug use review under state law and 42 CFR Part 456 for the purpose of identifying and resolving actual or potential drug-related problems, including, for example, therapeutic duplication, drug-drug interactions, incorrect drug dosage, drug-disease contraindication,

duration of drug treatment, or over-utilization or under-utilization and any other drug therapy problems outlined in [42 CFR § 456.705](#);

(2) Assist prescribers in obtaining a comprehensive drug history on a patient;

(3) Prevent abuse or misuse of any drug or device and the diversion of controlled substances; or

(4) Provide a medication therapy management program or a quality assurance program.

(b) Disclosure of information pursuant to this section shall not constitute a waiver of any confidentiality or privilege that may be provided by law.

(c) The provisions of this section shall apply only to confidentiality or privilege and shall not apply to actions arising in negligence.

→ **§ 63-10-213. Legibility of prescriptions issued by health care providers**

(a) No pharmacist may dispense medication pursuant to a handwritten, typed or computer-generated prescription order for a drug issued by a prescriber in this state, unless the prescription order is comprehensible to the pharmacist. Nothing in this section shall be construed to prohibit a pharmacist from dispensing medication pursuant to a verbal prescription order.

(b) If a prescriber issues a prescription order, then it is the duty of the prescriber to issue a legible order. A pharmacist shall make a reasonable attempt to contact the prescriber to seek clarification of a prescription order that is not comprehensible to the pharmacist, in which case the pharmacist must not dispense medication until the pharmacist obtains clarification. A pharmacist shall not be liable to any person for any reasonable delay caused when a pharmacist has reasonably sought clarification of a prescription order.

(c) Nothing in this section shall be construed to prevent a pharmacist from dispensing medication prior to authorization in accordance with [§ 63-10-207](#).

→ **§ 63-10-214. Centralized prescription processing; pharmacy licensure; rules**

(a) Each pharmacy participating in centralized prescription processing shall be licensed by the board of pharmacy.

(b) The board shall promulgate rules relative to centralized prescription processing, including, but not limited to, the usage of common electronic files or a common database.

→ § 63-10-215. Pharmacy generated prescription transfers

(a) Pharmacists, pharmacy interns and pharmacy technicians are authorized to comply with federal and state prescription requirements, including the requirement of a separate prescription for a Schedule II controlled substance found in §§ 63-3-128, 63-5-122(g), 63-6-239, 63-8-134, 63-9-118, 63-7-123(b)(3)(B) and (F), and 63-19-107(2)(E)(ii) and (2)(G), by transferring from a prescription containing a Schedule II controlled substance any drug that is a non-scheduled prescription drug or any prescribed supply to another prescription form.

(b) The transfer authorized in subsection (a) may be accomplished by scanning, photocopying or transcribing, by hand or other means, and shall include all information regarding each drug or supply being transferred.

(c) The prescription generated in a pharmacy by the transfer process shall not be required to be on tamper-resistant prescription paper.

(d) The prescription generated in a pharmacy utilizing the transfer process shall be recognized as a valid, legal prescription order and shall serve as the original prescription for recordkeeping and other purposes.

→ § 63-10-216. Compounding pharmacies; inspections; disciplinary actions; guidelines; report

(a) Prior to initial licensure in this state as a compounding pharmacy, a pharmacy located outside of this state must have an inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located. Out-of-state pharmacy practice sites must provide a copy of the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located, which must have been within the previous twelve (12) months. Prior to renewal of its license in this state, an out-of-state pharmacy practice site must provide the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located or equivalent regulatory entity, and which must have been within the previous twelve (12) months. The board of pharmacy shall have the right to require additional information before issuing or renewing a pharmacy license to insure compliance with applicable laws of this state and any rules and policies of the board.

(b) Any compounding pharmacy having an active Tennessee license shall notify the board within fourteen (14) business days of receipt of any order or decision by a regulatory agency, other than the Tennessee board of pharmacy, imposing any disciplinary action, including any warning, on the pharmacy.

(c) Any pharmacies engaged in sterile compounding must comply with relevant United States Pharmacopeia (USP) guidelines as adopted by the board by rule or policy.

(d) Any pharmacies engaging in sterile compounding, except hospital pharmacies compounding for inpatients of a hospital, shall report on a quarterly basis to the board the quantity of sterile compounded products dispensed in a defined time period in accordance with policies adopted by the board; provided, however, that

the executive director of the board may request this information from a hospital pharmacy for cause and the hospital pharmacy shall be required to respond in a timely manner as defined by the executive director of the board.

→ § 63-10-217. Repealed by 1996 Pub.Acts, c. 651, § 1, eff. January 1, 1997

Part 3. Board of Pharmacy (Refs & Annos)

→ § 63-10-301. Board; membership; powers and duties

(a) There shall exist and be maintained within this state a board of pharmacy. The board shall consist of seven (7) members, one (1) of whom shall be a consumer, who shall enforce parts 2-5 of this chapter and all laws that pertain to the practice of pharmacy and shall cooperate with other state and federal governmental agencies regarding any violations of any pharmacy drug or drug-related laws. The board has all of the duties, powers, responsibilities and authority specifically granted or necessary to the enforcement of parts 2-5 of this chapter, as well as other duties, powers, responsibilities and authority that may be granted by law.

(b) The members of the board shall be entitled to a per diem of one hundred dollars (\$100) for each day's service in attending meetings of the board and other administrative functions of the board, as well as the necessary expenses for traveling and subsistence while attending the meetings and performing the other administrative functions. All reimbursement for travel expenses shall be in accordance with the provisions of the comprehensive travel regulations as promulgated by the department of finance and administration and approved by the attorney general and reporter.

(c) The board of pharmacy shall publish a list of opioid drugs incorporating tamper or abuse resistance properties. Inclusion of a drug on such list shall not require that a drug bear a labeling claim with respect to reduction of tampering, abuse or abuse potential at the time of listing. The inclusion of a drug on the list shall not prohibit a pharmacist from substituting an opioid drug, brand or generic, that is otherwise eligible for interchange or substitution under title 53, chapter 10, part 2. The inclusion of a drug on the list shall require that the drug has been submitted to the United States food and drug administration with a study related to tamper or abuse resistance properties. Following the publication of the initial list by the board of pharmacy, if the United States food and drug administration approves an opioid drug that bears in its label a claim to the drug's tamper or abuse resistance properties, such drug shall be added to the board of pharmacy list. This list shall be made available to prescribers, pharmacists, the commissioner of health, the commissioner of mental health and substances abuse services and the commissioner of safety.

TERMINATION OF GOVERNMENTAL ENTITY

<The board of pharmacy, created by this section, is set to terminate June 30, 2016, by § 4-29-237. >

→ § 63-10-302. Board; qualifications and criteria; terms; recommendations; removal

(a) The governor shall appoint the members of the board and shall make appointments so that the pharmacist members of the board shall be graduates of a recognized school or college of pharmacy. In making appointments to the board, the governor shall strive to ensure that at least one (1) person serving on the board is sixty (60) years of age or older and that one (1) person serving on the board is a member of a racial minority.

(b) No pharmacist shall be eligible for appointment to the board unless such person has been a pharmacist under this or some other law of this state for a period of at least five (5) years and, during the terms of such person's incumbency, shall be actively engaged in the practice of pharmacy.

(c) No consumer shall be eligible for appointment to the board to represent the public at large unless such person has been a resident of Tennessee for at least five (5) years, currently resides in Tennessee and is a non-health care professional by education. The consumer member shall not own or have any financial or other interest in any health care facility or business.

(d) The terms of appointment shall be for six (6) years, or until their successors have qualified, and no member of the board is eligible for reappointment.

(e) Interested pharmacist groups, including, but not limited to, the Tennessee Pharmacists Association, may annually recommend five (5) duly qualified persons for each vacancy from whom the governor may be requested to make appointments. The governor shall consult with such groups to determine qualified persons to fill the positions. The appointment provisions of this subsection (e) shall not apply to the consumer member serving on the board. Appointees shall, within ten (10) days after appointment, make oath or affirmation to be filed with the secretary of state that they will faithfully and impartially perform their duties.

(f) Members guilty of misconduct may be removed by the governor upon the recommendation of the remaining members. Vacancies occurring other than by expiration of terms may be filled as to unexpired terms by the governor from the most recent list of nominees of the interested pharmacist groups as provided in subsection (e).

→ **§ 63-10-303. Board; officers; quorum; panels; executive director**

(a) The board shall have a president and a vice president, who shall be elected annually from its pharmacist members.

(b) A majority of the members of the board shall constitute a quorum. The board president may, when it is deemed necessary, split the board into panels of three (3) or more each to conduct contested case hearings or disciplinary matters. When the board is split into panels for purposes of contested case hearings and disciplinary matters, three (3) or more members shall constitute a quorum.

(c) The division shall employ on behalf of and in consideration of the recommendation of the board an executive director who shall be a pharmacist who has been licensed in Tennessee for a period of at least five (5) years. The executive director's duties shall be those specified by the board and by the director and may include, but not be limited to, recording and compiling the minutes of the board, supervising the employees assigned by the division to support the board, performing such studies and research as the board or division directs, representing the board at such functions as authorized by the board and the division and acting as consultant to the division in its enforcement duties on behalf of the board.

→ **§ 63-10-304. Board; authority; powers and duties**

(a) It is the duty of the board to enforce all the laws of the state now or hereafter enacted that pertain to the practice of pharmacy, the manufacture, distribution or sale of drugs, and the medication use process, including, but not limited to compounding, selection, preparation/production, dispensing/distribution, patient administration, education and monitoring of drugs, devices, chemicals or poisons. The division shall employ for the board the necessary administrative and clerical staff and investigators who are pharmacists to carry out the board's duty to enforce the pharmaceutical laws. The pharmacist investigators shall be authorized to conduct inspections of pharmacies and any other site where drugs, medicines, chemicals, pharmaceuticals or poisons are manufactured, stored, sold, dispensed, distributed or administered and shall conduct investigations of any licensee of the board. The pharmacist investigators may also assist in inspections and investigations undertaken by other health related boards attached to the division, and investigators assigned to these other health related boards may assist pharmacist investigators as appropriate.

(b)(1) The board shall adopt, amend and repeal rules for the proper administration and enforcement of parts 2-5 of this chapter, consistent with such provisions. The rules shall be adopted, amended or repealed in accordance with the Tennessee Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(2) The board shall adopt rules establishing minimum standards and conditions for operation of a pharmacy.

(3) If the board determines it necessary in order to protect the health and welfare of the citizens of this state, it may adopt rules concerning the practice of pharmacy in this state also applicable to the practice of pharmacy located in another state.

(c) The board also has the power and authority to adopt, amend and repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy.

(d) The board shall meet at least annually and at such other times as it deems necessary to perform its duties under this chapter.

(e) The board shall keep a record of all its proceedings. The board shall issue and maintain a register of all persons to whom licenses have been issued and all renewals and a register of pharmacists having been

designated as a pharmacist-in-charge. The board may maintain a register of pharmacy technicians as necessary to maintain public welfare.

(f)(1) The board is authorized to conduct hearings and issue orders concerning alleged violations of parts 2-5 of this chapter or rules promulgated pursuant to parts 2-5 of this chapter and shall retain jurisdiction over all of its orders to allow, when good cause is established, modification of those orders and the reinstatement or reactivation of any license or certificate that the board revoked or suspended pursuant to those orders.

(2) The board is authorized to petition any circuit or chancery court having jurisdiction of any person who is practicing pharmacy in Tennessee without a valid license or who has violated any of the provisions of parts 2-5 of this chapter or the rules of the board to enjoin that person from continuing to practice within this state.

(3) The director is granted authority to issue subpoenas for witnesses and records and to administer oaths to witnesses.

(g)(1) The board may join professional organizations and associations organized to promote the improvement of the standards of the practice of pharmacy for the protection of the health and welfare of the public.

(2) The board may authorize, subject to the approval of the commissioner, administrative and investigative personnel and board members to attend local, state, regional and national meetings and to perform other necessary functions. These personnel shall be reimbursed for all travel and other necessary expenses, which shall be claimed and paid in accordance with the prevailing travel regulations of state government.

(h) The board has the other duties, powers and authority necessary to enforce parts 2-5 of this chapter.

(i) The board shall adopt rules establishing minimum standards and conditions for receiving, preparing, maintaining, transferring and dispensing of prescription orders.

(j)(1) The board of pharmacy shall regularly notify each holder of a pharmacy or a pharmacist license of changes that are to be implemented or enforced by the board that affect the licensee. These changes shall include newly promulgated or amended statutes, rules, policies or guidelines.

(2) The board of pharmacy shall establish and maintain a link or links on the board of pharmacy web site to the statutes, rules, policies and guidelines that are implemented or enforced by the board and affect the licensee.

(3) The board of pharmacy shall mandate that the licensee maintain at the site of the licensee's practice a copy of the board of pharmacy statutes, rules, policies and guidelines.

→ § 63-10-305. Board; issuance or renewal of license; power and authority

The board is authorized to deny, restrict or condition any application for licensure or certification and is authorized to revoke or suspend any license or certification previously issued or otherwise discipline and assess civil penalties against a applicant, licensee or holder of a certificate upon a finding that the applicant, licensee or holder of a certificate has:

- (1) Been convicted of a crime;
- (2) Been convicted of violating any of the laws of this state or of the United States relating to drugs or to the practice of pharmacy;
- (3) Been addicted to the use of alcohol, narcotics or other drugs;
- (4) Engaged in conduct prohibited or made unlawful by any of the provisions of parts 2-5 of this chapter or any other laws of the state or of the United States relating to drugs or to the practice of pharmacy;
- (5) Exhibited an incapacity of a nature that prevents a pharmacist from engaging in the practice of pharmacy with reasonable skill, confidence and safety to the public;
- (6) Been guilty of dishonorable, immoral, unethical or unprofessional conduct;
- (7) Had the license to practice pharmacy suspended or revoked by another state for disciplinary reasons; or
- (8) Failed to comply with a lawful order or duly promulgated rule of the board.

→ § 63-10-306. Licensing; powers and procedures

- (a) Except as otherwise provided in parts 2-5 of this chapter, it is unlawful for any individual to engage in the practice of pharmacy unless currently licensed or otherwise authorized under parts 2-5 of this chapter to practice under any facet of the provisions of parts 2-5 of this chapter.
- (b) The board is authorized to establish the experience and education qualifications necessary for admission to the board's licensure or certification examination or examinations.
- (c) The board may utilize any national certification or licensure examination or contract any qualified examination agency to prepare and administer its licensure examination or examinations, and the board shall establish by rule the minimum score necessary to pass any licensure or certification examination or examinations required by the board.

(d) An applicant for licensure as a pharmacist shall be at least twenty-one (21) years of age, be a graduate of a school or college of pharmacy recognized by the board and submit an application for licensure on a form or forms approved by the board and pursuant to board rules and regulations.

(e) When satisfied that the qualifications of pharmacists licensed in other states are equivalent to or greater than requirements for licensure in this state, the board may grant licenses to reciprocal applicants from other states. The board may refuse to issue licenses to reciprocal applicants from other states on such grounds as the board may establish in its regulations.

(f) The board has the authority to license and register pharmacists, pharmacies, wholesalers, distributors, pharmacy technicians, manufacturers and such other persons as the board may be required to license under federal or state law upon requirements established by regulations of the board. This subsection (f) shall not be construed to include manufacturers' representatives, unless otherwise required by federal or state law.

(g) The board shall have the authority to establish the criteria, timing and procedure for renewal of licenses and certifications.

(h) The board is authorized to establish any and all necessary requirements for continuing education for those the board licenses or to whom the board issues certificates. This authority includes, but is not limited to, the establishment of the number of hours required, approval of providers and course content, enforcement and qualification for waiver of the requirements or extension of time in which to obtain the continuing education.

(i) The board shall define by rule the scope of practice of a pharmacy technician and the qualifications necessary to practice as a pharmacy technician. The board may designate by rule which national or other qualified pharmacy technician certification agencies will be recognized in this state for purposes of holding the status of a certified pharmacy technician.

→ **§ 63-10-307. Pharmacy practice site inspections; requirements; drug dispensing in physician's office**

(a) The board or its designated agents have the power and authority to regulate the practice of pharmacy and to inspect any site or professional pharmacy practice, other than storage sites utilized by manufacturer's representatives, where drugs, medicines, chemicals, pharmaceuticals or poisons are manufactured, stored, sold, dispensed, distributed or administered.

(b) Authority over drug dispensing in the office of a physician licensed to practice under chapter 6 of this title shall be vested in the board of medical examiners.

→ **§ 63-10-308. Fees**

(a) The board is authorized to establish fees necessary to carry out parts 2-5 of this chapter pursuant to duly

promulgated rules.

(b) All monies received by the board shall be deposited and dispensed pursuant to § 63-1-137.

→ **§ 63-10-309. Administrative Procedures Act; applicability**

The provisions of the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, shall govern all matters and procedures respecting the hearing and judicial review of any contested case as defined therein, arising under parts 2-5 of this chapter.

→ **§ 63-10-310. Transition**

For the purposes of transferring the board of pharmacy from the department of commerce and insurance to the department of health, the existing members of the board of pharmacy shall continue to serve as members of the Tennessee board of pharmacy until their terms expire. All rules and regulations of the state board of pharmacy shall remain in force and effect until modified, superseded or repealed by the board of pharmacy. All orders, decisions, licenses and certifications previously issued by the board of pharmacy or the department of commerce and insurance relating to or on behalf of the board of pharmacy shall remain in full force and effect and shall hereafter be administered and enforced by the department of health. To this end, the division of health related boards shall have the authority, consistent with the statutes and regulations pertaining to the programs and functions transferred in this section, to modify orders, decisions, licenses and certifications previously issued and to adopt and issue new orders as may be necessary for the administration of the programs or functions transferred in this section.

Part 4. Peer Review (Refs & Annos)

→ **§ 63-10-401. Legislative findings and declarations**

It is the policy of the state to encourage committees made up of Tennessee's licensed pharmacists to candidly, conscientiously and objectively evaluate their peers' professional conduct, competence and ability to practice pharmacy and their personal conduct as it relates to the performance of their professional duties. It is further the policy of the state to encourage pharmacists to implement continuous quality improvement programs and quality assurance programs to identify and evaluate quality-related events, reduce medication-related errors, generate data useful to studying the causes of medication errors and improve patient care. The state further recognizes that confidentiality is essential to effective functioning of peer review committees, continuous quality improvement programs and quality assurance programs and to continued improvement in patient safety and patient care.

→ **§ 63-10-402. Immunity from liability; good faith actions**

All national, state or local public or private organizations, institutions, foundations, systems, provider

networks or professional associations or societies, pharmacists, auxiliary pharmacy personnel, pharmacy committee staff personnel, any person under a contract or other formal agreement with a peer review committee and any person who participates with or assists a peer review committee, members of boards of directors or trustees of any public or private hospital, managed care organization or other health care provider or any individual appointed to any peer review committee is immune from liability to any patient, individual or organization for furnishing information, data, reports or records to any such committee or for damages resulting from any decision, opinions, actions and proceedings rendered, entered or acted upon by such committees, if made or taken in good faith without malice and on the basis of facts reasonably known or reasonably believed to exist.

→ **§ 63-10-403. Immunity from liability; information providers and witnesses**

Notwithstanding the provisions of § 63-10-402, any person providing information, whether as a witness or otherwise, to a peer review committee regarding the competence or professional conduct of a pharmacist or pharmacy auxiliary personnel is immune from liability to any person, unless such information is false and the person providing it had actual knowledge of its falsity.

→ **§ 63-10-404. Good faith presumptions; burden of proof**

A member of a peer review committee or any other person reporting information to a peer review committee is presumed to have acted in good faith and without malice. Any person alleging lack of good faith has the burden of proving bad faith and malice.

→ **§ 63-10-405. Privileged materials; confidentiality; waiver; exceptions**

(a) All information, interviews, reports, statements, memoranda or other data furnished to any peer review committee, association board, organization board or other entity and any findings, conclusions or recommendations resulting from the proceedings of such committee, board or entity are privileged. The records and proceedings of any peer review committee, board or entity are confidential and shall be used by such committee, board or entity, and the members thereof, only in the exercise of the proper functions of the committee, board or entity and shall not be public records nor be available for court subpoena or for discovery proceedings. One (1) proper function of a peer review committee includes advocacy for pharmacists and pharmacy auxiliary personnel before other peer review committees, health care organizations, insurance companies, national, state or local accreditation organizations, federal and state agencies and the board of pharmacy of this state or any other state. The disclosure of confidential, privileged peer review committee information during advocacy, or as a report to the board of pharmacy, or to the affected pharmacist or pharmacy auxiliary personnel under review does not constitute either a waiver of confidentiality or privilege. Nothing contained in this subsection (a) applies to records, documents or information otherwise available from original sources and such records, documents or information are not to be construed as immune from discovery or use in any civil proceedings solely due to presentation to the committee.

(b) All information, interviews, reports, statements, memoranda or other documents and materials created in the course of operation of a pharmacy continuous quality improvement program or quality assurance program shall be privileged and confidential and shall not be subject to discovery or subpoena or other means of legal process or introduction into evidence in any civil action, arbitration, administrative proceeding or state board of pharmacy proceeding. The pharmacy shall hold the privilege to all information, interviews, reports, statements, memoranda or other documents and materials created in the course of the pharmacy's continuous quality improvement program or quality assurance program. The privilege may be waived by the pharmacy. Nothing in this subsection (b) shall affect the discoverability of any records not solely generated for or maintained as a component of a pharmacy's ongoing continuous quality improvement program and quality assurance program.

(c) Nothing in subsection (b) shall be construed to prohibit a pharmacy from compiling, disclosing, reporting or otherwise using information or data that may be generated from the privileged and confidential documents and materials described in subsection (b), where the compiling, disclosing, reporting or otherwise using of the information or data is for the purpose of conducting research, providing education, reporting to federal or state patient safety or quality improvement databases, developing best practice guidelines or for similar other purposes, if personal information is redacted prior to disclosure.

→ **§ 63-10-406. Physicians; applicability**

In no event, however, shall the protections provided in this part apply to any type of review by a peer review committee or pharmacist review committee, as defined in this chapter, related to any acts, conduct or professional services rendered by physicians under chapter 6 or 9 of this title. A peer review committee or pharmacist review committee may convey information to licensed physicians or physician licensing boards.

→ **§ 63-10-407. Transferred to § 63-10-207 in 2004**

→ **§ 63-10-408. Transferred to § 63-10-208 in 2004**

→ **§ 63-10-409. Transferred to § 63-10-209 in 2004**

→ **§ 63-10-410. Transferred to § 63-10-210 in 2004**

→ **§ 63-10-411. Transferred to § 63-10-211 in 2004**

→ **§ 63-10-412. Transferred to § 63-10-212 in 2004**

→ **§ 63-10-413. Transferred to § 63-10-213 in 2004**

Part 5. Nina Norman Prescription Drug Donation Act of 2006 (Refs & Annos)**→ § 63-10-501. Short title**

This part shall be known and may be cited as the “Nina Norman Prescription Drug Donation Act of 2006.”

→ § 63-10-502. Purpose

It is the purpose of this part to:

- (1) Improve the health of needy Tennesseans through a prescription drug redispensing program that authorizes charitable clinic pharmacies to redispense medicines that would otherwise be destroyed; and
- (2) Reaffirm the existing broad latitude of the Tennessee board of pharmacy to protect the safety of the prescription drug supply in this state.

→ § 63-10-503. Definitions

As used in this part, unless the context otherwise requires:

(1) “Charitable clinic” means a charitable nonprofit corporation or a facility organized as a not-for-profit corporation under title 48 that:

(A) Holds a valid exemption from federal income taxation issued pursuant to the Internal Revenue Code, [26 U.S.C. § 501\(a\)](#);

(B) Is listed as an exempt organization under the Internal Revenue Code, [26 U.S.C. § 501\(c\)\(3\)](#);

(C) Provides advice, counseling, diagnosis, treatment, surgery, care or services relating to the preservation or maintenance of health on an outpatient basis for a period of less than twenty-four (24) consecutive hours to persons not residing or confined at the facility;

(D) May charge an administrative fee or request a donation not to exceed ten dollars (\$10.00) per visit; and

(E) Has an outpatient pharmacy licensed by the board of pharmacy;

(2) “Charitable clinic pharmacy” means a pharmacy practice site licensed by the board of pharmacy where prescriptions are dispensed free of charge by a pharmacist licensed by the board of pharmacy to indigent patients who have been appropriately screened and qualified by the charitable clinic;

- (3) “Controlled substances” means substances defined by § 63-10-204;
- (4) “Donor patient” means a patient, or the patient's representative in the event the patient is deceased or is not competent, who is the owner of the prescription drug and entitled to donate the drug for use by a charitable clinic pharmacy through an institutional facility;
- (5) “Indigent” means a person with an income that is below two hundred percent (200%) of the federal poverty level;
- (6) “Institutional facility” means a hospital, nursing home, home care organization, residential HIV supportive living facility or residential hospice facility as defined by § 68-11-201;
- (7)(A) “Prescription drug” means a drug defined by § 63-10-204;
- (B) “Prescription drug,” for purposes of this part, does not include controlled substances; and
- (8) “Properly transferred” means the storage, handling and distribution of the drug under this part is:
- (A) In accordance with the label; and
- (B) A dispensed, sealed, tamper-evident single user unit.

→ **§ 63-10-504. Prescription drug redispensing; pilot program; reports; participation**

- (a) The prescription drug redispensing program established by this part shall be a pilot program to determine the efficacy of redispensing prescription drugs to indigent patients.
- (b) The board of pharmacy, in cooperation with the department of health, shall develop and implement this pilot program consistent with public health and safety through which unused prescription medications, other than controlled substances, may be transferred from an institutional facility to a charitable clinic pharmacy for the purpose of distributing the medication to Tennessee residents who are indigent.
- (c) The board of pharmacy, in cooperation with the department of health, shall monitor the pilot program and submit two (2) reports along with any recommendations or findings to the health committees of the general assembly:
- (1) The first report on or before March 1, 2007; and

(2) The second report on or before January 1, 2008.

(d) Participation in this pilot program by any individuals or entities, including charitable clinics, charitable clinic pharmacies, drug manufacturers or institutional facilities, shall be voluntary.

→ **§ 63-10-505. Prescription drug acceptance and redispensing; valid prescription orders; contracts; donations; recalled drugs; Medicaid reimbursement; waiver form; rules; criminal liability**

(a) A charitable clinic pharmacy may accept for redispensing prescription drugs obtained from an institutional facility by the clinic pharmacy for relabeling and dispensing free of charge to an indigent patient pursuant to a valid prescription order.

(b)(1) Any institutional facility participating in the drug redispensing program established pursuant to this part shall enter into a contract with a charitable clinic pharmacy for the transfer of drugs pursuant to this section.

(2) No institutional facility may transfer drugs to any charitable clinic pharmacy pursuant to this section without entering into a contract as provided in subdivision (b)(1).

(3) A contract entered into pursuant to subdivision (b)(1) shall be approved by the board of pharmacy, in cooperation with the department of health.

(4)(A) A contract entered into under subdivision (b)(1) shall set out procedures for ensuring a safe chain of custody to protect the safety of all transferred drugs.

(B) The contract may specify that the charitable clinic pharmacy will either:

(i) Define a specified set of drugs that will be transferred from the institutional facility to the charitable clinic pharmacy;

(ii) Request from time to time the transfer of particular drugs;

(iii) Receive all the drugs that the institutional facility is authorized to transfer pursuant to this section; or

(iv) Make such other provisions as may be approved by the board of pharmacy.

(5) The pharmacist in charge at the charitable clinic shall be responsible for determining the description of the drugs that will be included in the contract.

(c) Donations of prescription drugs to a charitable clinic pharmacy shall meet the following requirements:

(1) The charitable clinic pharmacy shall accept the drugs only in their dispensed, sealed and tamper-evident packaging, which includes, but is not limited to, single-unit doses or blister packs with the outside packaging opened if the single-unit dose packaging remains intact;

(2) A pharmacist of the charitable clinic pharmacy shall determine that the drug is not adulterated or misbranded and is safe to dispense;

(3) No product of which the integrity cannot be assured shall be accepted for redispensing by the pharmacist of the charitable clinic pharmacy;

(4) The drugs shall be physically transferred from the institutional facility to a charitable clinic pharmacy by a person authorized by the state board of pharmacy to pick up the drugs for the charitable clinic pharmacy;

(5)(A) The donor patient shall execute a form stating that the donor is authorized to donate the drugs and intends to voluntarily donate them to a charitable clinic pharmacy;

(B) The institutional facility shall retain the donor form along with other acquisition records;

(6) The donor patient's name, prescription number, and any other identifying marks shall be obliterated from the packaging before the institutional facility sends the drug to the charitable clinic pharmacy;

(7) The drug name, strength and expiration date shall remain on the drug package label;

(8) The redispensed drug shall be assigned the same expiration date as on the original package;

(9) Expired drugs accepted by a charitable clinic pharmacy shall not be redispensed and shall be destroyed according to the charitable clinic pharmacy's destruction procedures; and

(10) The charitable clinic pharmacy shall accept no controlled substances.

(d)(1) If an institutional facility that releases drugs to a charitable clinic pharmacy receives notice from another pharmacy that a drug has been recalled, the institutional facility shall inform the charitable clinic pharmacy of the recall.

(2) If a charitable clinic pharmacy receives a recall notification from an institutional facility, the charitable clinic pharmacy shall perform a uniform destruction of all of the recalled drug in the charitable clinic

pharmacy.

(e) No drug dispensed through a charitable clinic pharmacy shall be eligible for reimbursement from the state medicaid program.

(f) Indigent patients receiving prescription drugs through this program shall sign a waiver form releasing the institutional facility, the donor patient and the donor patient's estate from liability.

(g) The board shall promulgate rules to develop:

(1) Forms and procedures for authorizations and certifications required under subdivision (c)(4);

(2) The donor consent form required under subdivision (c)(5);

(3) The waiver forms required under subsection (f); and

(4)(A) Specific requirements for a charitable clinic pharmacy or other specialty pharmacy for the medically indigent, as defined by rules of the board of pharmacy, to qualify for participation in and to participate in the pilot program;

(B) On request, the board shall provide the information required under subdivision (g)(4)(A) to charitable clinics.

(h)(1) The following persons and entities that participate in the pilot program shall not be subject to any criminal prosecution for actions taken under the program:

(A) The donor patient and the donor patient's estate;

(B) An institutional facility;

(C) The prescribing physician, physician's assistant, registered nurse, advanced practice nurse or nurse practitioner;

(D) The charitable clinic;

(E) The charitable clinic pharmacy acting in conformity with board of pharmacy regulations;

(F) Pharmacists and pharmacy technicians acting in conformity with the board of pharmacy regulations issued pursuant to this part;

(G) The department of health; or

(H) The board of pharmacy.

(2) Participation in the pilot program shall not be used as an independent basis for a claim of liability in tort or other civil action against any person or entity, including, but not limited to:

(A) The donor patient and the donor patient's estate;

(B) An institutional facility;

(C) The prescribing physician, physician's assistant, nurse practitioner or nurse;

(D) The charitable clinic;

(E) The charitable clinic pharmacy acting in conformity with board of pharmacy regulations;

(F) Pharmacists and pharmacy technicians acting in conformity with the board of pharmacy regulations issued pursuant to this part;

(G) The department of health; or

(H) The board of pharmacy.

(3) The following persons and entities that participate in the pilot program shall not be subject to any professional disciplinary action for action taken pursuant to this program:

(A) The donor patient or the donor patient's estate;

(B) An institutional facility;

(C) The prescribing physician, physician's assistant, nurse practitioner or nurse;

(D) The charitable clinic;

(E) The charitable clinic pharmacy acting in conformity with board of pharmacy regulations;

(F) Pharmacists and pharmacy technicians acting in conformity with board of pharmacy regulations;

(G) The department of health; or

(H) The board of pharmacy.

(4)(A) In the absence of bad faith, a drug manufacturer shall not be subject to criminal prosecution or liability in tort or other civil action for injury, death or loss to person or property for matters related to the donation, acceptance or dispensing of a drug manufactured by the drug manufacturer that is donated by a donor patient pursuant to the pilot program, including, but not limited to, liability for failure to provide:

(i) Product or consumer package insert information; or

(ii) The expiration date of the donated drug.

(B) Subdivision (h)(4)(A)(i) does not apply to a previously undisclosed product defect.

→ **§ 63-10-506. Physician drug samples**

Nothing in this part shall restrict the use of samples by a physician or advanced practice nurse during the course of working at a charitable clinic, whether or not the clinic has a licensed outpatient pharmacy.

→ **§ 63-10-507. Drug resale**

Nothing in this part shall be construed to provide for the resale of drugs by any person or entity.

→ **§ 63-10-508. Liability outside scope of pilot program**

Nothing in this part applies to any questions of liability arising outside the scope of the pilot program.

→ **§ 63-10-509. Transferred to § 63-10-309 in 2004**

→ **§ 63-10-510. Transferred to § 63-10-310 in 2004**

Part 6. Federally Qualified Health Center Prescription Drug Dispensing Pilot Program (Refs & Annos)**→ § 63-10-601. Prescription drugs issuance by technician**

(a) As used in this section, unless the context otherwise requires:

(1) “Federally qualified health center (FQHC)” means such entities as they are defined in §§ 1861 (aa) and 1905 of the federal Social Security Act, codified in [42 U.S.C. §§ 1395x](#) and [1396d](#); and

(2) “Telepharmacy in FQHCs” means an FQHC central pharmacy with one (1) or more FQHC remote sites in which all sites are connected via computer link, videolink and audiolink.

(b) Notwithstanding any other provision of this chapter, in an FQHC pilot project, as authorized in this section, a registered pharmacy technician employed by the FQHC is authorized to issue prescription drugs that have been filled by a pharmacist employed by the FQHC and delivered to the FQHC satellite clinic by an agent of the FQHC. The issuance of the prescription drugs may occur without the physical, on-site supervision of an on-duty pharmacist only under the conditions as provided in subsection (c). Registered pharmacy technicians performing services authorized in this section shall be permitted to function under the supervision of the FQHC pharmacist by means of telepharmacy with at least one (1) monthly on-site visit to review inventory controls, accountability, security, storage and issuance.

(c) In an FQHC pilot project, as authorized in this section, a registered pharmacy technician is authorized to issue prescription drugs to a patient of the FQHC and offer counseling by a pharmacist by means of telepharmacy. The FQHC pharmacist may provide patient counseling and supervision of the registered pharmacy technician when on duty at the pharmacy practice site of an FQHC.

(d) It is the intent of the general assembly that this section shall comply with all applicable requirements of the federal 340B drug pricing program, pursuant to § 340B of the Public Health Service Act, compiled in [42 U.S.C. § 256b](#), and shall apply exclusively to the uninsured or underinsured income-eligible patients of the FQHCs participating as defined in subsection (e) for whom the prescription is not covered by third-party reimbursement.

(e) On or after July 1, 2008, the department of health and the board of pharmacy shall identify one (1) FQHC for a voluntary pilot program originating in a county located in the eastern grand division of the state in order to implement the telepharmacy provisions at no more than two (2) eligible satellite clinics as described in this section. The eligible FQHC shall have an on-site pharmacy in one (1) location, eligible satellite clinics, be responsible for all costs associated with the telemedicine equipment and connectivity, have at least one (1) year of experience with telemedicine, adequate technical support, appropriate staffing, access to the patient's medical record and participate in the 340B drug pricing program. Only the approved pilot program in the FQHC shall be eligible for the supervision, delivery and issuance of prescription drugs to qualified patients as defined in subsection (d). This pilot program is not authorized to deliver or issue pharmaceutical products defined elsewhere as Schedule I, II, III or IV drugs. The pilot program shall report information regarding

patient satisfaction and safety to the board of pharmacy, the health and human resources committee of the house of representatives and the general welfare health and human resources committee of the senate by February 1, 2010. If the board of pharmacy determines that data demonstrates the pilot is successful, then the board may expand the project beyond the one (1) FQHC to as many FQHCs as it deems appropriate.

→ **§ 63-10-602. Board of pharmacy; rules**

The board of pharmacy shall adopt, amend and repeal rules for the proper administration and enforcement of parts 2-5 of this chapter consistent with the provisions of § 63-10-601. The rules shall be adopted, amended or repealed in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

→ **§ 63-10-603. Transferred to § 63-10-403 in 2004**

→ **§ 63-10-604. Transferred to § 63-10-404 in 2004**

→ **§ 63-10-605. Transferred to § 63-10-405 in 2004**

→ **§ 63-10-606. Transferred to § 63-10-406 in 2004**

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