

SENATE BILL 3660
By Haynes

AN ACT to amend Tennessee Code Annotated, Title 63 and Title 68, relative to allowing donated prescription medications to be dispensed at charitable clinics.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, is amended to add an additional part to read as follows:

63-10-501. 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.

63-10-502. As used in this part, unless 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 a licensed outpatient pharmacy;

(2) "Charitable clinic pharmacy" means the practice of a pharmacy at a site where prescriptions are dispensed by a charitable clinic free of charge to appropriately screened and qualified indigent patients;

(3) "Controlled substances" means substances defined by § 63-10-204;

(4) "Indigent" means a person with an income that is below two hundred percent (200%) of the federal poverty level;

(5) "Nursing home" means the same as under § 68-11-201;

(6)

(A)

(i) "Prescription drug" means a drug limited by § 503(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., to being dispensed by or upon a medical practitioner's prescription because the drug is:

(a) Habit-forming;

(b) Toxic or having potential for harm; or

(c) Limited in its use to use under a practitioner's supervision by the new drug application for the drug.

(ii) The product label of a legend drug is required to contain the statement:

(a) "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION"; or

(b) "Rx only".

(iii) The drug is subject to the requirement of § 503(b)(1) of the Federal Food, Drug, and Cosmetic Act which shall be exempt from § 502(f)(1) of the Federal Food, Drug, and Cosmetic Act if certain specified conditions are met.

(B) "Prescription drug", for purposes of this part, does not include controlled substances; and

(7) "Properly transferred" means the storage, handling, and distribution of the drug under this part in:

(A) Accordance with the label; and

(B) Its dispensed, sealed, tamper-evident single user unit.

63-10-503.

(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 human services and 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 a nursing home or a hospice services program 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 human services and the department of health, shall monitor the pilot program and submit two (2) reports along with any recommendations or findings to the general assembly:

(1) The first report on or before January 1, 2007; and

(2) The second report on or before October 1, 2007.

(d) Participation in this pilot program by any entity, including individuals, pharmacies, charitable clinics, charitable clinic pharmacies, hospice services programs, nursing facilities, and drug manufacturers shall be voluntary.

63-10-504.

(a)

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

(2) The donor patient shall be considered to be the owner of the prescription drug and entitled to donate the drug for use by a charitable clinic.

(b)

(1)

(A)

(i) Any nursing home or a hospice services program may enter into a contract with any charitable clinic for the transfer of drugs under this section.

(ii) No drugs may be transferred without a contract.

(B) A contract entered into under subdivision (b)(1)(A) shall be approved by the board of pharmacy, in cooperation with the department of human services and the department of health.

(2)

(A) A contract entered into under subdivision (b)(1)(A) 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 will either:

(i) Define a specified set of drugs that will be transferred from the nursing home or the hospice services program to the charitable clinic;

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

(iii) Receive all the drugs that the nursing home or the hospice services program is authorized to transfer under this section; or

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

(3) 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)

(A) The charitable clinic pharmacy accepts the drugs only in their original sealed and tamper-evident packaging;

(B) However, the charitable clinic pharmacy may accept drugs packaged in 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 determines that the drug is not adulterated or misbranded and is safe to dispense;

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

(4) The drugs are physically transferred from the nursing home or the hospice services program to a charitable clinic pharmacy by a person authorized by the state board of pharmacy to pick up the drugs for the charitable clinic;

(5)

(A) The donor executes 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 nursing home retains the donor form along with other acquisition records;

(6) The donor patient's name, prescription number, and any other identifying marks are obliterated from the packaging before the nursing home sends the drug to the charitable clinic;

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

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

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

(10) The charitable clinic pharmacy accepts no controlled substances.

(d)

(1) If a nursing home or a hospice services program that releases drugs to a charitable clinic receives notice from a pharmacy that a drug has been recalled, the nursing facility or the hospice services program shall inform the clinic of the recall.

(2) If a charitable clinic receives a recall notification from a nursing facility or a hospice services program, the clinic shall perform a uniform destruction of all of the recalled drug in the facility.

(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 nursing facility or the hospice services program, the donor, and the donor'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 professional disciplinary action or criminal prosecution for actions taken under the program:

- (A) The donor and the donor's estate;
- (B) A nursing facility or a hospice services program;
- (C) The prescribing physician, physician's assistant, registered nurse, advanced practice nurse, or nurse practitioner;
- (D) Pharmacists and pharmacy technicians except where the board has promulgated regulations dealing specifically with this program;
- (E) The charitable clinic;
- (F) The department of health;
- (G) The department of human services; 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 and the donor's estate;
- (B) A nursing facility or a hospice services program;
- (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) The pharmacist who originally dispensed the donated prescription drugs acting in conformity with board of pharmacy regulations;

(G) A pharmacist dispensing donated prescription drugs acting in conformity with board of pharmacy regulations;

(H) The department of health;

(I) The department of human services; or

(J) The board of pharmacy.

(3)

(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 any person under 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 (3)(A) does not apply to a previously undisclosed product defect.

63-10-505. 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.

63-10-506. Nothing in this part shall be construed to provide for the resale of drugs by any person or entity.

63-10-507. Nothing in this part applies to any questions of liability arising outside the scope of the pilot program.

SECTION 2. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 3. This act shall take effect July 1, 2006, the public welfare requiring it.