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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1056 Session of 2013

INTRODUCED BY SOLOBAY, ALLOWAY, VULAKOVICH, BROWNE, FERLO, FONTANA, BREWSTER, WASHINGTON, TARTAGLIONE, COSTA, WAUGH, BRUBAKER, SCHWANK AND BOSCOLA, JUNE 30, 2013

REFERRED TO CONSUMER PROTECTION AND PROFESSIONAL LICENSURE, JUNE 30, 2013

AN ACT

Providing for the establishment, implementation and administration of a program for the return of prescription drugs; and imposing additional powers and duties on the State Board of Pharmacy, the Department of Health and the Department of Public Welfare.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Prescription Drug Donation Program Act.

Section 2. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Approved clinic." An organized community-based clinic offering primary health care services to individuals and families who cannot pay for their health care, to medical assistance clients or to residents of medically underserved

areas or health professionals shortage areas, approved by the State Board of Pharmacy for the purpose of dispensing donated prescription drugs to patients who are indigent. The term may include a State health center, nonprofit community-based clinic as approved by the Department of Health or the Department of Public Welfare or a federally qualified health center, as designated by Federal regulation.

"Board." The State Board of Pharmacy of the Commonwealth.

"Closed drug delivery system." A system in which the control of a unit dose medication is maintained by a health care facility, health clinic, hospital, pharmacy or physician's office rather than an individual patient.

"Controlled substance." As defined in section 2 of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act.

"Health care facility." As defined in section 103 of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

"Health clinic." A for-profit or nonprofit clinic providing health services.

"Hospital." An entity licensed as a hospital under the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

"Pharmacist." A pharmacist licensed by the State Board of Pharmacy.

"Pharmacy." A pharmacy licensed by the State Board of Pharmacy.

"Physician's office." The office of a person licensed to practice medicine and surgery or osteopathic medicine and surgery.

"Prescribing practitioner." A health care practitioner licensed under the laws of this Commonwealth who is authorized to prescribe prescription drugs.

"Prescription drug." A drug that requires a prescription to be dispensed in this Commonwealth. The term includes a cancer drug, but does not include a controlled substance.

"Program." The Prescription Drug Donation Program established under section 3.

"Unit dose system." A system in which the individually sealed unit doses are physically connected as a unit.

"Vendor pharmacy." A licensed pharmacy participating in the program that inspects, packages, repackages or prepares a manufacturer-sealed container, unit dose package or unit of issue package of donated prescription drugs and distributes them to an approved clinic.

Section 3. Establishment.

The board shall establish a Prescription Drug Donation Program consistent with public health and safety standards through which a health care facility may donate unused prescription drugs to vendor pharmacies for inspection, repackaging and distribution of the donated drugs to approved clinics, which then dispense the drugs to persons who are residents of Pennsylvania and who meet the eligibility requirements of the program. Participation in the program shall be voluntary.

Section 4. Eligibility requirements for participating entities.

Eligibility requirements for participating entities are as follows:

(1) An entity participating in the program must be approved by the board for the purpose of receiving,

distributing and dispensing donated prescription drugs.

(2) A participating vendor pharmacy must be licensed by the board.

(3) A participating approved clinic must be licensed by the Department of Health.

(4) A participating vendor pharmacy and approved clinic must comply with all Federal and State laws, rules and regulations applicable to the storage and distribution of drugs.

(5) A participating vendor pharmacy and approved clinic must comply with the State laws, rules and regulations applicable to the program.

Section 5. Eligibility requirements for recipients of donated prescription drugs.

Recipients of donated prescription drugs must meet the following eligibility requirements:

(1) An individual who receives a donated prescription drug from an approved clinic must be a resident of Pennsylvania.

(2) The income of a recipient under this act may not exceed 200% of the Federal poverty level.

Section 6. Acceptance and restocking of prescription drugs.

A health care facility that is part of a closed drug delivery system may return to a vendor pharmacy a prescription drug under the following conditions:

(1) the prescription drug must be in the original unopened, sealed and tamper-evident unit dose packaging. A prescription drug packaged in single-unit doses may be accepted if the outside packaging is opened but the single-unit dose packaging is unopened or not tampered with;

(2) the donated prescription drug retains the drug name, strength, manufacturer identifier, lot and expiration date as originally labeled by the pharmacy or manufacturer. The prescription drug cannot be accepted by a vendor pharmacy if the prescription drug bears an expiration date that is earlier than six months after the date the prescription drug was restocked, or the prescription drug is adulterated or misbranded or the prescription drug requires storage temperatures other than normal room temperature as specified by the manufacturer and United States Pharmacopoeia; or

(3) in the case of controlled substances, as it is allowed by Federal law.

A prescription drug that may only be dispensed to a patient registered with the drug's manufacturer in accordance with the requirements of the Food and Drug Administration may not be accepted or distributed under the provisions of the program.

Section 7. Inspection, repackaging and distribution of donated prescription drugs.

The following apply to the inspection, repackaging and distribution of donated prescription drugs:

(1) The pharmacist at a vendor pharmacy shall determine by examination, testing or other investigation that donated prescription drugs are not adulterated or misbranded.

(2) The pharmacist at a vendor pharmacy shall determine that the conditions under which the drug has been delivered, stored and handled before and during return to the pharmacy have preserved proper integrity, stability and labeling of the drug and that the drug labeling or packaging has not been altered or defaced and the drug name, strength, manufacturer identifier, lot and expiration date are retrievable.

(3) If repackaging and relabeling are required, a vendor pharmacy shall repackage and relabel donated prescription drugs in accordance with the rules and regulations of the board.

(4) A vendor pharmacy shall distribute returned prescription drugs to an approved clinic upon request by the approved clinic if the requested prescription drugs are available.

(5) A vendor pharmacy may charge an approved clinic, if necessary, a repackaging and relabeling fee equal to no more than the maximum dispensing fee authorized by the Department of Public Welfare regulations under the medical assistance program.

Section 8. Dispensing of donated prescription drugs.

(a) General rule.--An approved clinic may dispense donated prescription drugs in compliance with applicable Federal and State laws and regulations for dispensing prescription drugs. The prescription drugs shall only be dispensed by an approved clinic pursuant to a prescription issued by a prescribing practitioner.

(b) Fee.--An approved clinic may charge the recipient of a donated drug a handling fee, equal to no more than the maximum dispensing fee authorized by the Department of Public Welfare regulations under the medical assistance program.

Section 9. Storage of donated prescription drugs.

A vendor pharmacy that accepts donated prescription drugs and an approved clinic that dispenses donated prescription drugs under the program shall:

(1) Comply with all applicable provisions of Federal and State law relating to the storage of prescription drugs.

(2) Store donated prescription drugs in a location separate from other drugs.

Section 10. Recordkeeping.

The following recordkeeping requirements shall apply:

(1) A vendor pharmacy shall record and log the exact quantity, name and strength of donated prescription drugs upon receipt from a health care facility, and prior to distributing the drugs to an approved clinic.

(2) An approved clinic that receives donated prescription drugs from a vendor pharmacy shall record the receipt and verify the quantity, name and strength of the drugs.

(3) An approved clinic shall keep a complete record of the drugs dispensed under this program to eligible individuals.

(4) Records required as part of the program shall be maintained separately from other records.

Section 11. Immunity.

A person or entity, acting in good faith, who exercises reasonable care in donating, accepting, distributing, dispensing or manufacturing prescription drugs donated and utilized under the program shall be immune from civil or criminal liability or professional disciplinary action for any injury, death or loss to a person or property relating to activities under the program. The immunity includes, but is not limited to, immunity from liability for failure to transfer or communicate product or consumer information or the expiration of the donated prescription drug. Immunity granted under this section is solely applicable to the donation, acceptance, distribution, dispensing or manufacture of the actual medication donated to the program

and is explicitly not a general waiver of liability.

Section 12. Regulations.

The board shall promulgate regulations to carry out the purposes of this act within 90 days of the effective date of this section. The regulations shall include:

(1) Income eligibility criteria and other standards and procedures for individuals participating in the program, determined by the Department of Public Welfare in conjunction with the board.

(2) Standards and procedures for inspecting donated drugs to determine that the original unit dose packaging is sealed and tamper-evident and that the drugs are unadulterated, safe and suitable for dispensing.

(3) Necessary forms for administration of the program, including forms for use by entities permitted to accept, distribute or dispense donated prescription drugs under the program.

(4) Categories of prescription drugs that the program will accept for dispensing and categories of prescription drugs that the program will not accept for dispensing and the reason that the prescription drugs will not be accepted.

(5) Informed consent forms for recipients of donated prescription drugs through the program indicating that the prescription drugs have been restocked and redistributed.

(6) Provisions for recalls of the prescription drug if necessary.

(7) Procedures for entities participating in the program to minimize theft and diversion.

(8) Any other regulations the board deems necessary to implement and administer the program.

Section 20. Effective date.

This act shall take effect in 60 days.