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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2363 Session of 2024

INTRODUCED BY CUTLER, GREINER, PICKETT, KINSEY, MOUL, STAATS, ROWE, STENDER, SCHEUREN, GILLEN, HADDOCK, E. NELSON AND MENTZER, JUNE 3, 2024

AS REPORTED FROM COMMITTEE ON HEALTH, HOUSE OF REPRESENTATIVES, AS AMENDED, JUNE 12, 2024

AN ACT

Amending the act of May 13, 2008 (P.L.139, No.14), entitled "An act establishing the Cancer Drug Repository Program for accepting donated cancer drugs and dispensing cancer drugs; and providing for the powers and duties of the State Board of Pharmacy," further providing for title and short title of act, for definitions, for establishment of program, for restocking and dispensing of cancer drugs, for storage, distribution and fees and for immunity, providing for annual report and for list of approved participating pharmacies and further providing for regulations.

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

Section 1. The title and sections 1, 2, 3, 4, 5(a) and (b) and 6 of the act of May 13, 2008 (P.L.139, No.14), known as the Cancer Drug Repository Program Act, are amended to read:

AN ACT

Establishing the [Cancer] Prescription Drug Repository Program for accepting donated [cancer] prescription drugs and dispensing [cancer] prescription drugs; and providing for the powers and duties of the State Board of Pharmacy.

Section 1. Short title.

This act shall be known and may be cited as the [Cancer] Prescription Drug Repository 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:

"Adulterated." As specified under section 7 of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act.

"Approved participating pharmacy." A pharmacy approved by the State Board of Pharmacy for the purpose of dispensing unused [cancer] prescription drugs to participating entities and to patients who are indigent.

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

"Cancer drug." A prescription drug used to treat any of the following:

(1) Cancer or its side effects.

(2) The side effects of a prescription drug used to treat cancer or its side effects.

["Closed drug delivery system." A system in which the actual 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 Controlled Substance, Drug, Device and Cosmetic Act.

"Health care facility." [A for-profit or nonprofit entity providing clinically related health services, including those operated by the Commonwealth or its political subdivisions and including a general or special hospital, including psychiatric hospitals, rehabilitation hospitals, ambulatory surgical

facilities, long-term care nursing facilities, a hospice, a cancer treatment center using radiation therapy on an ambulatory basis and an inpatient drug and alcohol treatment facility.] As defined in section 802.1 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.

"MANUFACTURER." AS DEFINED IN SECTION 2 OF THE CONTROLLED SUBSTANCE, DRUG, DEVICE AND COSMETIC ACT. <--

"Misbranded." As specified under section 8 of The Controlled Substance, Drug, Device and Cosmetic Act.

"Pharmacist." A pharmacist licensed by the Commonwealth.

"Pharmacy." A pharmacy licensed by the Commonwealth.

"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 [cancer] prescription drugs.

"Prescription drug." A drug requiring a prescription in this Commonwealth. The term includes cancer drugs. The term does not include a controlled substance.

"Program." The [Cancer] Prescription Drug Repository Program established in section 3.

["Unit dose system." A system wherein all individually sealed unit doses are physically connected as a unit.]

"WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS." AS DEFINED IN <--

SECTION 3 OF THE ACT OF DECEMBER 14, 1992 (P.L.1116, NO.145), KNOWN AS THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS LICENSE ACT.

Section 3. Establishment.

The board shall establish a [Cancer] Prescription Drug Repository Program consistent with public health and safety standards through which unused [cancer] prescription drugs may be redispensed to [cancer] patients by pharmacies approved by the board for the purpose of dispensing unused [cancer] prescription drugs to residents who are indigent. The board shall develop and promulgate rules and regulations to establish procedures necessary to implement the program. Participation in the program shall be voluntary.

Section 4. Restocking and dispensing of [cancer] prescription drugs.

An [entity that is part of a closed drug delivery system] individual, health care facility, hospital ~~or~~, health clinic, MANUFACTURER OR WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS may return OR DONATE to an approved participating pharmacy an unused [cancer] prescription drug under the following conditions: <--

(1) [If the cancer] The prescription drug is in its original unopened, sealed and tamper-evident [unit dose] packaging. A [cancer] prescription drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened.

(2) The [cancer] prescription drug may not be accepted or dispensed by the approved participating pharmacy if the [cancer] prescription drug bears an expiration date that is earlier than six months after the date the [cancer]

prescription drug was restocked or the [cancer] prescription drug is adulterated or misbranded.

[(3) Except as provided in this subsection, an unused cancer drug dispensed under a State medical assistance program may be accepted and dispensed by the approved participating pharmacy.

(4) In the case of controlled substances, as it is allowed by Federal law.]

(5) SUBJECT TO THIS ACT AND EXCEPT AS OTHERWISE PROHIBITED BY FEDERAL OR STATE LAW, AN UNUSED PRESCRIPTION DRUG DISPENSED UNDER A STATE MEDICAL ASSISTANCE PROGRAM MAY BE ACCEPTED AND DISPENSED BY AN APPROVED PARTICIPATING PHARMACY. <--

Section 5. Storage, distribution and fees.

(a) General rule.--An approved participating pharmacy that accepts donated [cancer] prescription drugs under the [Cancer] Prescription Drug Repository Program shall comply with all applicable provisions of Federal and State law **[**relating to**]**, INCLUDING the storage, distribution and dispensing of [cancer] prescription drugs and shall inspect all [cancer] prescription drugs prior to dispensing to determine if they are adulterated or misbranded. The [cancer] prescription drugs shall only be dispensed by a pharmacist according to State law pursuant to a prescription issued by a prescribing practitioner. The [cancer] prescription drugs may be distributed to another participating physician's office, pharmacy, hospital or health clinic for dispensing by a pharmacist as allowed by Federal or State law. <--

(b) Handling fee.--An approved participating pharmacy may charge a handling fee for distributing or dispensing [cancer] prescription drugs under the program. The fee shall be

established in regulations promulgated by the board. [Cancer] Prescription drugs donated under the program shall not be resold.

* * *

Section 6. Immunity.

Any person or entity, acting in good faith, who exercises reasonable care in donating, accepting, distributing, dispensing or manufacturing [cancer] 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. Immunity granted under this section is solely applicable to the donation, acceptance, distribution, dispensing or manufacture of the actual medications donated to the program and is explicitly not a general waiver of liability.

Section 2. The act is amended by adding sections to read:

Section 6.1. Annual report.

(a) Report.--The board shall report annually by December 31 of each year on the progress in implementing and administering this act and submit the report to all of the following:

(1) The chairperson and minority chairperson of the Health and Human Services Committee of the Senate.

(2) The chairperson and minority chairperson of the Health Committee of the House of Representatives.

(3) The chairperson and minority chairperson of the Consumer Protection and Professional Licensure Committee of the Senate.

(4) The chairperson and minority chairperson of the Professional Licensure Committee of the House of

Representatives.

(b) Contents.--A report under subsection (a) shall include all of the following information:

(1) The name and address of each approved participating pharmacy in the program.

(2) The number of approved participating pharmacies in the program by county.

(3) The number of approved participating pharmacies that have withdrawn from the program.

(4) The number of pharmacies that the board has refused to approve, has revoked or has suspended from participating in the program.

(5) Recommendations to the General Assembly for improvements or changes to the program as the board deems necessary.

Section 6.2. List of approved participating pharmacies.

The board shall post on the board's publicly accessible Internet website a list of each approved participating pharmacy, including the address and telephone number of each approved participating pharmacy. The board shall update the list under this section within 30 days of a change in the list and note the change from the previous list on the board's publicly accessible Internet website.

Section 3. Section 7 of the act is amended to read:

Section 7. Regulations.

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

(a) Authority.--In order to facilitate the prompt implementation of this act, the board may promulgate temporary

regulations that shall expire no later than two years following the publication of the temporary regulations. The board must promulgate the temporary regulations within 180 days of the effective date of this subsection. The board may promulgate temporary regulations not subject to:

(1) Section 612 of the act of April 9, 1929 (P.L.177, No.175), known as The Administrative Code of 1929.

(2) Sections 201, 202, 203, 204 and 205 of the act of July 31, 1968 (P.L.769, No.240), referred to as the Commonwealth Documents Law.

(3) Sections 204(b) and 301(10) of the act of October 15, 1980 (P.L.950, No.164), known as the Commonwealth Attorneys Act.

(4) The act of June 25, 1982 (P.L.633, No.181), known as the Regulatory Review Act.

(b) Expiration.--The board's authority to adopt temporary regulations under subsection (a) shall expire two years after the effective date of this subsection. Regulations adopted after this period shall be promulgated as provided by law before the expiration of the temporary regulations under subsection (a).

(c) Contents.--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] Human Services in conjunction with the board.

(2) Eligibility criteria and other standards and procedures for entities participating in the program that restock and distribute or dispense donated [cancer] prescription drugs.

(3) Necessary forms for administration of the program,

including forms for use by entities permitted to accept, distribute or dispense [cancer] prescription drugs under the program.

(4) The maximum handling fee that may be charged by entities permitted to restock and distribute or dispense donated [cancer] prescription drugs.

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

(6) Informed consent provision for patients participating in the program indicating that the [cancer] prescription drug has been restocked and redistributed.

(7) Provisions for recalls of the drug if necessary.

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

(d) Applicability.--The regulations promulgated by the board as published in the Pennsylvania Bulletin at 43 Pa.B. 7011 (November 27, 2013) and effective November 30, 2013, shall remain in full force and effect until the promulgation of the temporary regulations under subsection (a).

Section 4. This act shall take effect in 60 days.