PROPOSED RULEMAKING

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Cancer Drug Repository Program

The State Board of Pharmacy (Board) proposes to add §§ 27.501—27.506 (relating to Cancer Drug Repository Program) to read as set forth in Annex A.

Effective Date

The proposed rulemaking will be effective upon final-form publication in the *Pennsylvania Bulletin*.

Statutory Authority

The proposed rulemaking is authorized under section 6(k)(9) of the Pharmacy Act (act) (63 P. S. § 390-6(k)(9)) and sections 3 and 7 of the Cancer Drug Repository Program Act (CDRPA) (62 P. S. §§ 2923 and 2927).

Background and Need for the Proposed Rulemaking

The CDRPA (62 P. S. §§ 2921—2927) created the Cancer Drug Repository Program (Program) to permit pharmacies to voluntarily accept donated cancer drugs and to dispense those drugs to indigent persons as provided in the CDRPA. It also authorizes and requires the Board to promulgate regulations to implement the CDRPA, including income eligibility criteria, pharmacy eligibility and standards, necessary forms, maximum handling fee, categories of drugs to be accepted, informed consent provisions, drug recall provisions, and theft and diversion minimization procedures. Upon promulgation, this proposed rulemaking would fulfill the Board's obligations under the CDRPA.

Description of the Proposed Rulemaking

The proposed rulemaking would add six new sections to the Board's regulations to implement the Program. Proposed § 27.501 (relating to purpose) specifies that these sections implement the CDRPA. Proposed § 27.502 (relating to definitions) provides the necessary definitions from the CDRPA.

Proposed § 27.503 (relating to participation in the Cancer Drug Repository Program) addresses application processes and eligibility criteria for participation in the Program. Subsection (a) provides that a pharmacy holding a current unrestricted permit may participate in the Program in accordance with the regulations and the CDRPA. Subsection (b) sets forth the information to be included on a pharmacy's application for approval to participate in the Program. Subsection (c) sets forth three criteria for a pharmacy's eligibility to participate in the Program. Along with possessing a current unrestricted permit in good standing, and agreeing to participate in the Program in accordance with applicable law, the applicant pharmacy must delegate to a licensed pharmacist the responsibility to receive donations at the designated delivery area in the pharmacy. This will provide a level of involvement, control and supervision by an individual licensed by, and answerable to, the Board, as opposed to a pharmacy intern or technician. Subsection (d) provides the criteria as to who may make a donation of cancer drugs and supplies, as well as what information about the drug or supply must be provided in writing by the donor at the time of donation. Subsection (e) sets forth the Board's authority to refuse, revoke or suspend its approval of a pharmacy's participation in the Program and the occasions upon which it may elect to exercise that authority.

Proposed § 27.504 (relating to drugs) addresses drugs that are eligible for the Program. Subsection (a) requires that the drug be in its original unopened, sealed and tamper-evident unit dose packaging or, if the outside packaging is opened but the single-unit-dose packaging is unopened, be packaged in single unit doses. As defined in proposed § 27.502, the term "original sealed and tamper-evident unit dose packaging" means single unit dose packaging of oral medications from a manufacturer or a repackager licensed with the United States Food and Drug Administration (FDA) or from a licensed pharmacy and includes injectables, topicals and aerosols in the manufacturer's or repackager's unopened original tamper-evident packaging. This implements the requirement of section 4(1) of the CDRPA (62 P. S. § 2924(1)) that a cancer drug accepted for donation must be in its original unopened, sealed and tamper-evident unit dose packaging, though outside packaging may be opened if the single-unit-dose packaging is unopened.

Under proposed § 27.504(b)(1), a pharmacy could not accept a drug bearing an expiration date that is earlier than 6 months after it will be restocked. Under subsection (b)(2), a pharmacy could not accept a drug that is adulterated or misbranded.

Proposed § 27.504(b)(3) excludes drugs designated by the United States Drug Enforcement Agency (DEA) as a controlled substance under 21 CFR Part 1308 (relating to schedules of controlled substances). The DEA determined that an individual patient may not return unused controlled substance prescription medication to a pharmacy. Federal laws and regulations do not make provisions for an individual to return a controlled substance prescription medication to a pharmacy for further dispensing or disposal. There are no provisions in the Controlled Substances Act (21 U.S.C.A. §§ 801—904) for a DEA registrant to acquire controlled substances from a nonregistrant. Federal laws and regulations do not make provisions for controlled substances that have already been dispensed to patients, regardless of the packaging method, to be returned to a pharmacy for further dispensing or disposal.

Proposed § 27.504(b)(4) excludes drugs whose distribution the FDA has restricted under 21 CFR 314.520 or 314.610 (relating to approval with restrictions to assure safe use; and approval based on evidence of effectiveness from studies in animals). Examples of this type of drug are thalidomide and lenalidomide. The purpose of this exclusion is to minimize the possibility that health care professionals unaware of the specific registration requirements for distribution of these drugs may inadvertently facilitate their ingestion by patients.

Additionally, because the effectiveness and safety of a cancer drug requiring refrigeration cannot be assured without continued refrigeration, proposed § 27.504(b)(5) excludes drugs that require refrigeration. Lastly, because compounded prescription drugs are designed to meet a particular patient's specific needs, subsection (b)(6) excludes drugs that have been previously compounded.

Proposed § 27.504(c) provides that, unless otherwise ineligible, a pharmacy may accept a cancer drug in any of the categories of the American Hospital Formulary Ser-

vice Pharmacologic—Therapeutic Classification. Proposed § 27.504(d) requires that a pharmacy handle the recall of any drug in the Program as if the drug had come directly from the manufacturer.

Proposed § 27.505 (relating to repositories) addresses the repository site. Under subsection (a), a participating pharmacy would have to designate a drop-off site within the pharmacy at which its licensed pharmacist shall personally receive, and acknowledge in writing, donations of cancer drugs. Subsection (b) requires the pharmacy's compliance with Federal and State laws regarding storage, distribution, dispensing, disposal and destruction of cancer drugs. It also requires the pharmacy to inspect donated cancer drugs for adulteration or misbranding prior to dispensing. Subsection (b) also requires that donated cancer drugs be dispensed only by a licensed pharmacist under a prescription issued by a prescribing practitioner. Under subsection (c), a participating pharmacy would be required to dispose of donated drugs that it does not accept into the Program. To better assure compliance with the storage and other requirements of participation, proposed § 27.505(d) requires a pharmacy to store the cancer drugs separately from other drugs in the pharmacy's stock.

Proposed § 27.505(e) sets forth the specific information that a pharmacy must provide to a patient. This information constitutes the basis of the patient's informed consent and shall be presented to the patient on a written form. The patient shall sign the informed consent form before the pharmacy dispenses the cancer drug to that patient. The form must contain information regarding the donation of the drug or supply. It must further state that the drug or supply may have been previously dispensed but was unused, that it was donated to the pharmacy in its original sealed and tamper-evident packaging to be restocked and redistributed, that the pharmacist conducted a visual inspection to ensure that the drug was in its original, unopened packaging and had not expired or been adulterated or misbranded. The form also must contain a provision that, while the pharmacist has determined that the drug or supply appears to be safe for dispensing or administering, the safety of the drug or supply cannot be guaranteed.

Proposed § 27.505(f) requires recordkeeping to be easily auditable and account for every dose and that the pharmacy use forms developed by the Board for receipt and dispensing of the drug. The proposed forms are available upon request. Subsection (g) would limit the handling fee that a pharmacy may charge up to 250% of the current $4 Medical Assistance (MA) dispensing fee in 55 Pa. Code § 1121.55 (relating to method of payment). Subsection (h) would require the participating pharmacy to have a policy to deter theft and diversion.

Proposed § 27.506 (relating to patient eligibility) would address patient eligibility for the Program. Subsection (a) sets forth the patient status eligibility criteria: being diagnosed with cancer; not possessing or possessing only limited prescription drug coverage regarding the treatment of cancer; and being ineligible for the State MA Program that provides prescription drug coverage regarding the treatment of cancer. Subsection (b) addresses patient financial eligibility for the Program. It would limit participation to those individuals meeting the family income standard published by the Department of Public Welfare based upon income not exceeding 350% of the Federal Poverty Income Guidelines and may not otherwise have insurance that would cover the cancer drugs. Appendix A provides the current income amounts for eligibility in the Program.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking will not have adverse fiscal impact on the Commonwealth or its political subdivisions. The proposed rulemaking will impose additional paperwork requirements upon the Board in the form of the processing of applications for participation in the Program and it also contains recordkeeping requirements for the regulated community.

Sunset Date

The Board continuously monitors the effectiveness of its regulations. Therefore, a sunset date has not been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on March 2, 2011, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to David M. Green, Counsel, State Board of Pharmacy, P. O. Box 2649, Harrisburg, PA 17105-2649, st-pharmacy@state.pa.us within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference No. 16A-5423 (Cancer Drug Repository Program), when submitting comments.

RICHARD R. SMIGA, RPh,
Chairperson

Fiscal Note: 16A-5423. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

CANCER DRUG REPOSITORY PROGRAM

§ 27.501. Purpose.

This section and §§ 27.502—27.506 establish a Cancer Drug Repository Program under the Cancer Drug Repository Program Act (62 P. S. §§ 2921—2927) through which unused cancer drugs may be redispensed to cancer patients by pharmacies approved by the Board for the purpose of dispensing unused cancer drugs to residents who are indigent.

§ 27.502. Definitions.

The following words and terms, when used in §§ 27.501 and 27.503—27.506, have the following meanings, unless the context clearly indicates otherwise:

Cancer drug—A prescription drug used to treat:

(i) Cancer or its side effects.

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

Original sealed and tamper-evident unit dose packaging—Single unit dose packaging of oral medications from a manufacturer or a repackager licensed with the Federal Food and Drug Administration, or from a licensed pharmacy, and includes injectables, topicals, and aerosols in the manufacturer's or repackager's unopened original tamper-evident packaging.

§ 27.503. Participation in the Cancer Drug Repository Program.

(a) *Participation*. A pharmacy holding a current unrestricted permit may apply for approval to participate in the Cancer Drug Repository Program as an approved cancer drug repository as provided in this chapter.

(b) *Application*. A pharmacy may apply for approval to participate in the Cancer Drug Repository Program by submitting the following information to the Board, on a form provided by the Board:

(1) The name, street address and telephone number of the pharmacy.

(2) Identification and background information of the pharmacy's ownership.

(3) Description of all pharmacy services provided and the location and manner in which those services are provided.

(4) The name and telephone number of a licensed pharmacist who is employed by or under contract with the pharmacy.

(5) A certification of a licensed pharmacist who is employed by or under contract with the pharmacy that the pharmacy meets the eligibility requirements for participation in the Cancer Drug Repository Program under subsection (c).

(c) *Eligibility*. A pharmacy is eligible to participate in the Cancer Drug Repository Program if:

(1) The pharmacy holds a current unrestricted permit in good standing to operate as a pharmacy in this Commonwealth.

(2) The pharmacy delegates to a licensed pharmacist employed by or under contract with the pharmacy the responsibility to receive delivery of donated prescription drugs or medical supplies at the designated delivery area in the pharmacy.

(3) The pharmacy agrees to participate in the Cancer Drug Repository Program in accordance with the act, this chapter and the Cancer Drug Repository Program Act (62 P. S. §§ 2921—2927).

(d) *Donations of cancer drugs and supplies.*

(1) An individual who is 18 years old or older or a pharmacy, medical facility, drug manufacturer or wholesale drug distributor may donate legally obtained cancer drugs or supplies to an approved participating pharmacy if the drugs or supplies meet the eligibility requirements under § 27.504 (relating to drugs) as determined by a licensed pharmacist employed by or under contract with an approved participating pharmacy.

(2) To be considered for donation, a cancer drug or supply must be accompanied by a cancer drug repository donor form on a form provided by the Board that:

(i) Is signed by the person or entity making the donation or that person's or entity's authorized representative.

(ii) States that to the best of the donor's knowledge the donated drug or supply has been properly stored and that the drug or supply has never been opened, used, tampered with, adulterated or misbranded.

(e) *Changes in approval status.* The Board may refuse, revoke or suspend approval of a pharmacy's participation in the Cancer Drug Repository Program upon proof satisfactory to it that the pharmacy has violated the Cancer Drug Repository Program Act, the act, or any Federal or State law, rule or regulation.

§ 27.504. Drugs.

(a) *Eligible drugs*. Unless otherwise prohibited by Federal or State statute or regulation, a cancer drug may be accepted by a licensed pharmacist at an approved participating pharmacy for dispensing in a Cancer Drug Repository Program if the drug meets one of the following criteria:

(1) The drug is in its original unopened, sealed and tamper-evident unit dose packaging.

(2) The drug is packaged in single unit doses, when the outside packaging is opened but the single-unit-dose packaging is unopened.

(b) *Ineligible drugs*. A cancer drug may not be accepted by a licensed pharmacist at an approved participating pharmacy for dispensing if the drug meets any one of the following criteria:

(1) The drug bears an expiration date that is earlier than 6 months after the date the drug will be restocked.

(2) The drug shows evidence of having been adulterated or misbranded.

(3) The drug is designated by the Drug Enforcement Agency as a controlled substance under 21 CFR Part 1308 (relating to schedules of controlled substances).

(4) The drug is subject to restricted distribution by the Food and Drug Administration under 21 CFR 314.520 or 314.610 (relating to approval with restrictions to assure safe use; and approval based on evidence of effectiveness from studies on animals).

(5) The drug requires refrigeration, freezing or other special temperature requirements beyond controlled room temperature.

(6) The drug has been previously compounded.

(c) *Drug categories*. Unless otherwise ineligible under this section, an approved participating pharmacy may accept a cancer drug in any of the categories of the American Hospital Formulary Service Pharmacologic—Therapeutic Classification.

(d) *Recalls*. An approved participating pharmacy shall handle a recall of any drug in its Cancer Drug Repository Program as if the drug had been delivered directly to the pharmacy by the manufacturer.

§ 27.505. Repositories.

(a) *Donation site receipt*. An approved participating pharmacy shall designate an area within the pharmacy at which its licensed pharmacist shall personally receive delivery from the donor or its designee, and provide the donor or its designee with written acknowledgement of any donation of a cancer drug.

(b) *Donation site compliance*. An approved participating pharmacy that accepts donated cancer drugs under the Cancer Drug Repository Program shall comply with all applicable Federal and State law relating to the storage, distribution, dispensing, disposal and destruction of cancer drugs and inspect all cancer drugs prior to dispensing to determine if they are adulterated or misbranded. The cancer drugs shall only be dispensed by a licensed pharmacist according to State law pursuant to a prescription issued by a prescribing practitioner.

(c) *Disposition*. The approved participating pharmacy repository shall destroy or dispose of donated drugs if they are not accepted into the Cancer Drug Repository Program for the purpose of dispensing. A record of destruction or disposal of donated drugs and supplies that are not accepted or dispensed under the Cancer Drug Repository Program shall be maintained by the participating pharmacy for at least 2 years, and include the following:

(1) The date of destruction.

(2) The name, strength and quantity of the cancer drug destroyed.

(3) The name of the person or firm that destroyed the drug.

(4) The source of the drugs or supplies destroyed.

(d) *Storage*. Drugs received in the Cancer Drug Repository Program shall be stored separately from the rest of the approved participating pharmacy's stock.

(e) *Informed consent*. Prior to dispensing a cancer drug in its Cancer Drug Repository Program, an approved participating pharmacy shall inform the patient that the drug was previously dispensed but was unused and then donated to the approved participating pharmacy in the drug's original sealed and tamper-evident unit dose packaging to be restocked and redistributed. The approved participating pharmacy may not dispense the drug if the patient does not sign a cancer drug repository informed consent form as supplied by the Board. The informed consent form shall be maintained for at least 2 years after the patient signs it. The form must include the following information:

(1) The drug or supply being dispensed has been donated and may have been previously dispensed.

(2) The drug was unused, although previously dispensed.

(3) The drug was donated to the approved participating pharmacy in the drug's original sealed and tamper-evident packaging to be restocked and redistributed.

(4) A visual inspection has been conducted by the pharmacist to ensure that the drug has not expired, has not been adulterated or misbranded, and is in its original, unopened packaging.

(5) The dispensing pharmacist, the prescribing or administering practitioner, the cancer drug repository, the Board and any other participant of the Cancer Drug Repository Program cannot guarantee the safety of the drug or supply being dispensed or administered, and that the pharmacist has determined that the drug or supply appears to be safe to dispense or administer based on the accuracy of the donor's form submitted with the donated drug or supply and the visual inspection required to be performed by the pharmacist before dispensing or administering.

(f) *Recordkeeping*. Drugs used in the Cancer Drug Repository Program must be easily auditable and every dose accounted for by the approved participating pharmacy's maintenance of recordkeeping meeting the following requirements:

(1) The approved participating pharmacy must record receipt of the drug on a repository donor form as developed by the Board.

(2) The approved participating pharmacy must record dispensing the drug on a repository dispensing form as developed by the Board.

(3) The approved participating pharmacy shall record the following information for all cancer drugs received, dispensed and distributed or disposed of or destroyed in the Cancer Drug Repository Program:

(i) Name and strength of the cancer drug.

(ii) Quantity of the cancer drug.

(iii) Expiration date of the cancer drug.

(iv) Lot number of the cancer drug.

(v) Name of pharmacy that originally dispensed the cancer drug.

(vi) Name of the donor of the cancer drug.

(vii) Name of the person to whom the cancer drug was originally prescribed, if applicable.

(viii) Name of the person to whom the cancer drug was dispensed.

(ix) Date the cancer drug was dispensed.

(x) Name of the prescribing practitioner who wrote the prescription for the cancer drug to be dispensed under the Cancer Drug Repository Program.

(xi) Date the cancer drug was disposed of or destroyed.

(xii) Whether a handling fee was charged and the amount of the fee.

(4) The approved participating pharmacy shall maintain records required under this section for at least 2 years.

(g) *Handling fee*. An approved participating pharmacy may charge a handling fee for distributing or dispensing cancer drugs under the Cancer Drug Repository Program, not to exceed 250% of the Medical Assistance dispensing fee more specifically set forth in the Method of Payment for Pharmaceutical Services provided in 55 Pa. Code Chapter 1121 (relating to pharmaceutical services). (See 55 Pa. Code § 1121.55 (relating to method of payment).) Cancer drugs donated under the Cancer Drug Repository Program may not be resold.

(h) *Theft and diversion*. An approved participating pharmacy shall develop, implement and enforce a policy to deter and minimize theft and diversion of cancer drugs it receives in the form of donations made pursuant to the Cancer Drug Repository Program.

§ 27.506. Patient eligibility.

(a) *Conditions of eligibility*. To be eligible for the Cancer Drug Repository Program, a patient must meet the following criteria:

(1) The patient is diagnosed with cancer.

(2) The patient does not possess or has limited prescription drug coverage related to the treatment of the patient's cancer so that the coverage limits prevent the patient from obtaining cancer drugs.

(3) The patient does not meet the eligibility requirements under the State Medical Assistance Program that provides prescription drug coverage related to the treatment of cancer.

(b) *Financial eligibility for the Cancer Drug Repository Program.*

(1) A Pennsylvania resident who meets the eligibility requirements in subsection (a) is financially eligible as an "indigent patient" for the Cancer Drug Repository Program if the resident meets the income standards in this subsection.

(2) The income limits for eligibility for the Cancer Drug Repository Program are based upon family income not to exceed 350% of the current Department of Health and Human Services Federal Poverty Income Guidelines for the appropriate family size. The current income limits for eligibility for the Cancer Drug Repository Program are in Appendix A. Revisions to the income limits will be published as a notice in the *Pennsylvania Bulletin* for codification.

(3) There are no resource limits for determining eligibility under the Cancer Drug Repository Program.

APPENDIX A

INCOME LEVELS FOR THE CANCER DRUG REPOSITORY PROGRAM

Family Size	*Monthly Income Limit*	*Annual Income Limit*
1	$3,034	$36,400
2	$4,084	$49,000
3	$5,134	$61,600
4	$6,184	$74,200
5	$7,234	$86,800
6	$8,284	$99,400
Each Additional Person	$1,050	$12,600

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