Regulatory Analysis Form

(Completed by Promulgating Agency)

SECTION I: PROFILE

(1) Agency:
Department of State, Bureau of Professional and Occupational Affairs, State Board of Pharmacy

(2) Agency Number: **16A**

Identification Number: **5423**

IRRC Number: 2889

(3) Short Title:
Cancer Drug Repository Program

(4) PA Code Cite:
49 Pa. Code §§ 27.501-27.506

(5) Agency Contacts (List Telephone Number, Address, Fax Number and Email Address):

Primary Contact: **Kerry E. Maloney, Board Counsel, State Board of Pharmacy; (717)783-7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; kmaloney@pa.gov**

Secondary Contact: **Cynthia K. Montgomery, Regulatory Counsel, Department of State (717)783-7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; cymontgome@pa.gov**

(6) Primary Contact for Public Comments (List Telephone Number, Address, Fax Number and Email Address) – Complete if different from #5: **State Board of Pharmacy (717)783-7156; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-7769; st-pharmacy@pa.gov**

(All Comments will appear on IRRC'S website)

(7) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- X Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

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(8) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The final form rulemaking would implement the Cancer Drug Repository Program Act (62 P.S. §§ 2921-2927).

(9) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments:	**April 11, 2011**
B. The date or dates on which public meetings or hearings will be held:	**N/A**
C. The expected date of promulgation of the proposed regulation as a final-form regulation:	**Spring 2013**
D. The expected effective date of the final-form regulation:	**upon publication as final**
E. The date by which compliance with the final-form regulation will be required:	**effective date**
F. The date by which required permits, licenses or other approvals must be obtained:	**N/A**

(10) Provide the schedule for continual review of the regulation.

The Board continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The Board reviews its regulatory proposals at regularly scheduled public meetings, generally the third Tuesday of each month. More information can be found on the Board's website (www.dos.state.pa.us/pharmacy).

SECTION II: STATEMENT OF NEED

(11) State the statutory authority for the regulation. Include specific statutory citation.

This rulemaking is authorized by 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 (62 P.S. §§ 2923 and 2927).

(12) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

Yes, the Cancer Drug Repository Program Act (62 P.S. §§ 2921-2927) requires the Board to promulgate regulations to implement its provisions. The proposed rulemaking is not mandated by any other Federal or State law or court order or Federal regulation.

(13) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The General Assembly recognized the compelling interest in enacting the Cancer Drug Repository Program Act. Eligible persons needing cancer drugs who cannot otherwise afford them may benefit from the rulemaking. Healthcare facilities, pharmacies and medical practices that have excess cancer drugs will also benefit from the rulemaking by being able to donate those drugs.

(14) If scientific data, studies, references are used to justify this regulation, please submit material with the regulatory package. Please provide full citation and/or links to internet source.

This proposed rulemaking is not based upon any scientific data, studies, or references.

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(15) Describe who and how many will be adversely affected by the regulation. How are they affected? **The Board does not foresee any groups being adversely affected by the proposed rulemaking.**
(16) List the persons, groups or entities that will be required to comply with the regulation. Approximate the number of people who will be required to comply. **All pharmacists and pharmacies that choose to participate in the Cancer Drug Repository Program will be required to comply with the provisions of this rulemaking. Although there are approximately 3,400 pharmacies currently registered, the Board cannot estimate how many will participate in the Program.**

SECTION III: COST AND IMPACT ANALYSIS

(17) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There may be costs to pharmacies that choose to participate in the Cancer Drug Repository Program, however, the Board is unable to calculate with reasonable certainty what those costs may be. The existence of these costs, if any, would depend on several unknown and unknowable factors including how many pharmacies choose to participate, how many cancer drugs are donated to a particular pharmacy, whether the pharmacy has existing space and manpower to participate in the Program or would need additional resources, whether the immunity granted by the statute has any effect on liability insurance premiums associated with participation in the program, etc. Any estimate of increased costs would be speculative at best. And a pharmacy could avoid those costs by simply electing not to participate in this voluntary program.

As to savings for eligible cancer patients, according to the American Cancer Society, the average cost of a 30-day cancer drug prescription was more than $1,600 in 2006, and it is even higher today. Many cancer drugs cost more than drugs for other illnesses. Some of the newer cancer treatments can cost as much as $10,000 for a month's supply. However, estimating the potential savings would also depend on several unknowable factors. First, savings would depend on how many eligible cancer patients would take advantage of the Program. Second, cost savings would depend on how much of the patient's prescribed medication is available through the Program. It seems unlikely that *all* of the patient's cancer drug regimen would be available. Also, the amount available may vary from month to month, and the patient's drug regimen may vary, depending upon the patient's therapeutic responses to previously prescribed medications and the advancement of the disease. Finally, as noted above, cancer drugs vary greatly in cost depending on the particular drug or combination of drugs involved.

For all of these reasons, the Board finds that it is unable to estimate the possible costs to participating pharmacies or the possible savings to eligible cancer patients with any meaningful figures.

(18) Provide a specific estimate of the costs and/or savings to **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no costs or savings to local governments associated with compliance with the proposed rulemaking.

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(19) Provide a specific estimate of the costs and/or savings to **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no costs or savings to state government associated with compliance with the proposed rulemaking.

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

NOTE: The Board is unable to estimate the costs to participating pharmacies or the savings to eligible patients. The Board does not mean to imply that there aren't any potential costs or savings, just that any estimation is speculative at best.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	$	$	$	$	$	$
Regulated Community						
Local Government						
State Government						
Total Savings	**Unknown**	**Unknown**	**Unknown**	**Unknown**	**Unknown**	**Unknown**
COSTS:						
Regulated Community						
Local Government						
State Government						
Total Costs	**Unknown**	**Unknown**	**Unknown**	**Unknown**	**Unknown**	**Unknown**
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**

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(20a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY –3 (FY 09-10)	FY –2 (FY 10-11)	FY –1 (FY 11-12)	Current FY (FY 12-13)
Pa. State Board of Pharmacy	**actual $1,748,926**	**actual $1,933,061**	**actual $2,004,201**	**projected $2,052,000**

(21) Explain how the benefits of the regulation outweigh any cost and adverse effects.

The benefits to eligible cancer patients (being able to receive donated cancer drugs at no cost) would appear to outweigh any costs to pharmacies who choose to participate in the Cancer Drug Repository Program.

(22) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

The Board solicited early meaningful input in accordance with Executive Order 1996-1 by releasing an exposure draft of the rulemaking and received input from the following interested parties: Jerry Musheno, R.Ph., Esq., Adjunct Assistant Professor, Wilkes University Nesbitt School of Pharmacy; Melanie Horvath, Executive Director, Pennsylvania Pharmacy Council; Patricia A. Epple, Executive Director, Pennsylvania Pharmacists Association (PPA); Brian G. Swift, Pharm.D., MBA, Vice President and Chief Pharmacy Officer, Jefferson University Hospitals, Inc.; and Samia M. Nasr, Division of New Drugs and Labeling Compliance, Office of Compliance, CDER, FDA. In addition, the Board worked with the Department of Public Welfare in drafting the rulemaking. The Board published the proposed rulemaking in the *Pennsylvania Bulletin* for public comment on March 12, 2011. At that time the Board received public comments from the PPA, the FDA, the Pennsylvania Medical Society (Society) and the Pennsylvania Society of Oncology and Hematology (PSOH). The rulemaking was discussed at public meetings of the Board, which are routinely attended by members of the regulated community and their professional associations.

(23) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory schemes were considered.

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(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations

The rulemaking is not more stringent and does not overlap or conflict with any Federal requirements.

(25) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete with other states?

There are states that have a similar drug repository program for cancer patients and other chronic diseases that are uninsured or underinsured. Some of those states permit donations by individuals outside of a closed drug delivery system. Others include medical supplies. Some states have programs for specific types of facilities such as long term care facilities and correctional institutions. The rulemaking would not put Pennsylvania at a competitive disadvantage.

(26) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

This proposed regulation would not affect other regulations of the Board or other state agencies.

(27) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

This proposed rulemaking would require the following new forms (attached in proposed format): Application for Prescription Drug Repository; Donor Form; Donation, Transfer and Destruction Record; Recipient Record; and Notice of Participation or Withdrawal.

(28) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The Board has determined that there are no special needs of any subset of its applicants or licensees for whom special accommodations should be made.

CANCER DRUG REPOSITORY APPLICATION INSTRUCTIONS

Please review all program requirements under the Commonwealth of Pennsylvania, State Board of Pharmacy's Cancer Drug Repository Program 49 Pa. Code §27.501 - 27.506 before completing the Cancer Drug Repository Application. All questions must be thoroughly answered. A response or explanation must be provided for all questions. An approval may be delayed if appropriate responses to all questions are not provided.

I. Applicant Information

A. Application Type – Please indicate the services the applicant is seeking to provide in the Commonwealth. Select one option only.
B. Please provide all requested information about the pharmacy or health care facility where the service will be provided.
C. The legal applicant is the individual that is authorized to respond to questions and make any decision regarding the operation of the pharmacy or health care facility. This individual may or may not be the same person that completes the application.

II. Ownership Description – Attach a list of the owners and corporate officers, for all levels of ownership. Include the following on the attachment: Name, Title, Percent ownership, Business address, Telephone number, and Fax number.

A. Indicate the date that the pharmacy/facility initially opened.
B. Indicate the date of the most recent inspection by the State Board of Pharmacy and/or other health care facility licensing body in the Commonwealth.
C. Attach a detailed explanation about any violations (federal, state or local convictions) as requested.
D. Indicate the type of ownership (select only one). If a corporation, list principal owners, indicate the corporate name, charter state and date of charter, and indicate whether it is a Public or Non-Public corporation.

III. BUSINESS OPERATIONS

A. Indicate all applicable descriptions of the pharmacy.
B. Indicate all applicable descriptions of the health care facility services.
C. If the pharmacy/health care facility conducts business on the internet, describe the services and web site business name(s).
D. Indicate the hours of operation for each day of the week.
E. Personnel – List employees' names who will be accepting and dispensing donated prescription drugs or medical supplies, in addition to their scheduled hours and license/permit numbers and expiration dates. The Board must be notified in 30 days of any changes in pharmacists/health care practitioners employment.

IV. CERTIFICATION – Each item must be read and initialed by the legal applicant.

V. LEGAL SIGNATURE – The statement must be read and signed by the legal applicant.

Commonwealth of Pennsylvania
State Board of Pharmacy
P.O. Box 2649, Harrisburg, PA 17105-2649
Phone - (717) 783-7156
Fax - (717) 787-7769
ST-PHARMACY@state.pa.us

APPLICATION FOR CANCER DRUG REPOSITORY

Date Received: _____ **Date Approved:** _____
Number: _____ **Initials:** _____

Please refer to instruction for completing the Application. Approval may be delayed if appropriate responses to all questions are not provided.

I. APPLICANT INFORMATION: DATE:_____

A. APPLICATION TYPE:

_____ **Repository**
_____ **Drop-off Site**
_____ **Repository and Drop-Off Site**

B. APPLICANT FACILITY INFORMATION:

1._____
PHARMACY/HEALTH CARE FACILITY NAME-DOING BUISNESS AS (DBA) OR TRADE NAME

2._____
CURRENT PERMIT/LICENSE NUMBER

3._____
STREET ADDRESS

_____
CITY **STATE** **ZIP CODE**

4._____
BUSINESS TELEPHONE NUMBER **BUSINESS FAX NUMBER**

5._____
WEB SITE ADDRESS **E-MAIL ADDRESS** **FEDERAL TAX ID NO.**

C. PHARMACY/HEALTH CARE FACILITY CONTACT INFORMATION:

1. Legal Representative:

_____
Name **Title** **Telephone** **Fax**

2. Person Completing Application:

_____
Name **Title** **Telephone** **Fax**

II. Ownership Description:

A. Date Established:_____

B. Date of Last Board or other Commonwealth Inspection:_____

C. Has the corporation or any officers thereof, or any partners, or the individual owner ever been convicted of violations of any federal, state or local laws or regulations dealing with drug products or alcohol?

_____ **No** _____ **Yes,** **(If yes, attach a detailed explanation)**

D. Ownership information is attached: Yes ____ No ____

_____ **Individual Ownership**
_____ **Partnership**
_____ **Corporation**

Corporate Name: _____

Principal Owner(s): _____

Charter State/Date: _____/_____ **Non-Public** _____ **Public** _____

III. BUSINESS OPERATIONS

A. TYPE OF PHARMACY SERVICES:

_____ Community (less than 10)	_____ Clinic	_____ Research
_____ Hospital	_____ Managed Care	_____ Mail Order/Internet
_____ Chain (10 + Stores)	_____ Nuclear	_____ Nursing Home
_____ Long Term Care	_____ Correctional Institution	_____ HMO
_____ Intravenous Therapy	_____ Home Health	_____ Consultant
_____ Mail Order/Internet/USA	_____ Independent	_____ Other (specify below)
_____ Veterinary	_____ Pharmacy Service Center	_____

_____

B. TYPE OF HEALTH CARE FACILITY CERVICES:

_____ Hospital	_____ Long Term Care	_____ Home Health
_____ Nursing Home	_____ Day Care	_____ HMO
_____ Free Clinic	_____ Clinic	_____ Managed Care
_____ Other (specify below)		

_____

C. Services Provided Through the Internet? _____ **No** _____ **Yes**

1. Specify Services: _____

2. Website Business Name(s): _____

_____

D. Hours of Operation:

Sunday	_____	Thursday	_____
Monday	_____	Friday	_____
Tuesday	_____	Saturday	_____
Wednesday	_____		

PERSONNEL – **Personnel accepting and dispensing donated cancer drugs:**

Name:	Employment: Full-time Part-time:	Pa. License/ Registration No.:	Expiration Date:

IV. CERTIFICATION: (please initial)

_____ a. I hereby certify that the pharmacy/health care facility is equipped with sanitary appliances such as toilets, plumbing, running water, lighting, etc. in order to maintain the premises in a clean and orderly manner.

_____ b. I hereby certify that the pharmacy /health care facility meets the requirements of the attached Regulations regarding the Cancer Drug Repository Program

_____ c. I hereby certify that the pharmacy/health care facility does not have a final disciplinary order issued against it by the State Board of Pharmacy or another health-related board.

_____ d. I hereby certify that the owner or operator of the pharmacy/health care facility has fulfilled any requirements of a final disciplinary order that may have been issued against the owner or operator by the State Board of Pharmacy or another health-related board.

V. LEGAL SIGNAURE: I understand that obtaining approval to be a repository or a drop-off site by making false representations may result in the revocation of approval to operate a repository or drop-off site in Pennsylvania. By signing this application, I solemnly affirm under the penalties of perjury that the contents of this application are true to the best of my knowledge, information, and belief.

_____

Signature of Legal Applicant | Business Telephone Number | Business Fax Number

_____

Typed Name and Title | E-mail Address

CANCER DRUG REPOSITORY PROGRAM

DONOR FORM

Date of Donation: _____

Name of Donor: _____

Address: _____

_____

Phone number: _____

Email address (optional): _____

List of donated cancer drugs: _____

_____

_____

_____

_____

_____

_____

I hereby certify that I am the owner or the owner's representative of the cancer drug donated today. My donation of the cancer drug to the program is voluntary.

_____

Signature of donor

STATE BOARD OF PHARMACY
P.O. Box 2649
Harrisburg, PA 17105-2649

COMMONWEALTH OF PENNSYLVANIA

CANCER DRUG REPOSITORY PROGRAM
DONATION, TRANSFER AND DESTRUCTION RECORD

Completion of this form meets the requirements under The Cancer Drug Repository Program Act, 62 P.S. §§2921-2927 for donating drugs and supplies, for distribution of drugs or supplies to a participating repository and for destruction of drugs or supplies under the Cancer Drug Repository Program. This form must be maintained for at least five (5) years.

Questions about completing this form may be directed to 717-783-7156.

DONATION INFORMATION

Name – Donor (print or type)	Date Donated

Name – Pharmacy or Medical Facility Receiving Donation

Name – Medication

Medication Strength	Expiration Date	Lot Number	Quantity Donated

I certify that the above named drug or supply was stored as recommended by the manufacturer and that the drug has never been opened, used, tampered with, adulterated, or misbranded.

SIGNATURE – Donor or Designee	Date Signed

Name of pharmacist accepting donation	License number of pharmacist

DISTRIBUTION OF DONATED CANCER DRUG TO A PARTICIPATING REPOSITORY

A COPY of the original donation form must accompany this form for all distributions between participating repositories

Name – Pharmacy or Medical Facility Receiving Drug	Date Distributed

Quantity of Medication Distributed

DESTRUCTION OR DISPOSAL INFORMATION

Name, Strength and Quantity

Source of Drug

Name of Person or Firm Destroying or Disposing of Drug

STATE BOARD OF PHARMACY
P.O. Box 2649
Harrisburg, PA 17105-2649

COMMONWEALTH OF PENNSYLVANIA

CANCER DRUG REPOSITORY PROGRAM
RECIPIENT RECORD

Completion of this form meets the requirements under The Cancer Drug Repository Program Act, 62 P.S. §§2921-2927 for dispensing or administrating cancer drugs to recipients who meet the eligibility requirements of the Cancer Drug Repository Program. This form must be maintained for at least five (5) years.

Questions about completing this form may be directed to 717-783-7156.

RECIPIENT INFORMATION

Name – Recipient (print or type)	Date Received

Name – Medication

Medication Strength	Expiration Date	Lot Number	Quantity Received

I certify that I am a Pennsylvania Resident, I meet the eligibility requirements of 49 Pa. Code § 27.506 (relating to patient eligibility) to participate in the Cancer Drug Repository Program, and that I understand that the above named drug I am receiving has been donated, may have been previously dispensed, and has potentially been stored in a non-controlled environment. I understand that a visual inspection has been conducted by the pharmacist or practitioner to ensure that the drug has not expired, has not been adulterated or misbranded and is in its original manufacturer's unopened packaging. I understand that the dispensing pharmacist, the administering practitioner, the cancer drug repository, the State Board of Pharmacy, and any other participant of the cancer drug repository program cannot guarantee the safety of the drug being dispensed or administered and that the pharmacist or practitioner has determined that the drug is 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 or practitioner before dispensing or administering.

SIGNATURE – Recipient	Date Signed

STATE BOARD OF PHARMACY
P.O. Box 2649
Harrisburg, PA 17105-2649

COMMONWEALTH OF PENNSYLVANIA

CANCER DRUG REPOSITORY PROGRAM
NOTICE OF PARTICIPATION OR WITHDRAWAL

Completion of this form meets the notification requirement for participation in or withdrawal from, the Cancer Drug Repository Program under The Cancer Drug Repository Program Act, 62 P.S. §§2921-2927. Complete and submit this form to the following address. Questions about completing this form may be directed to 717-783-7156. This form must be maintained for at least five (5) years.

State Board of Pharmacy
P.O. Box 2649, Harrisburg, PA 17105-2649
Phone - (717) 783-7156
Fax - (717) 787-7769

NOTICE OF PARTICIPATION
PHARMACY OR MEDICAL FACILITY

A Pharmacy or medical facility may fully participate in the cancer drug repository program by accepting, storing and dispensing donated cancer drugs or may limit its participation to only accepting and storing donated cancer drugs.
Check one of the following:

☐ Full Participation (Will dispense cancer drugs.) ☐ Partial Participation (WILL NOT dispense cancer drugs.)

Name – Pharmacy or Medical Facility	Telephone Number	
Address		
City	State	Zip Code
Name – Pharmacist	License Number	Telephone Number

I certify that the above named facility is licensed in the Commonwealth of Pennsylvania and is in compliance with all State and Federal laws and administrative rules.

SIGNATURE – Pharmacist	Date Signed

NOTICE OF WITHDRAWAL
PHARMACY OR MEDICAL FACILITY

Name – Pharmacy or Medical Facility	Telephone Number	
Address		
City	State	Zip Code

As of (enter date) _____ the pharmacy or medical facility identified above, will no longer be participating in the Cancer Drug Repository Program.

SIGNATURE – Pharmacist	Date Signed

CDL-1

RECEIVED
IRRC

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FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

BY: _____
(DEPUTY ATTORNEY GENERAL)

_____
DATE OF APPROVAL

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

State Board of Pharmacy
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-5423

_____
DATE OF ADOPTION:

BY: _____
Edward J. Bechtel, RPh

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Copy below is approved as to form and legality.
Executive or Independent Agencies.

BY: _____
Shawn E. Smith

4/15/13
DATE OF APPROVAL

(Deputy General Counsel
(Chief Counsel,
Independent Agency
(Strike inapplicable title)

[ ] Check if applicable
Copy not approved.
Objections attached.

[ ] Check if applicable.
No Attorney General approval or objection within 30 day after submission.

FINAL RULEMAKING

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY

49 Pa. Code §§ 27.501-27.506

Cancer Drug Repository Program Regulations

The State Board of Pharmacy (Board) hereby adds §§ 27.501-27.506 (relating to cancer drug repository program), to read as set forth in Annex A.

Effective date

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

Statutory Authority

The amendments are 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 Purpose

The Cancer Drug Repository Program Act (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 requires the Board to promulgate regulations to implement the CDRPA.

Summary of Comments and Responses to Proposed Rulemaking

The Board published notice of proposed rulemaking at 41 Pa.B. 1337 (March 12, 2011), followed by a 30-day public comment period. The Board received comments from The Pennsylvania Medical Society; the Pennsylvania Society of Oncology and Hematology (PSOH); the U.S. Department of Health and Human Services, Food and Drug Administration (FDA) and the Pennsylvania Pharmacists Association (PPA). The Board also received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) as part of their review of proposed rulemaking under the Regulatory Review Act (71 P.S. §§ 745.1-745.12). The Board did not receive comments from the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC).

General Comments

The FDA commented generally that it is opposed to any medication reuse and redispensing programs because of the risks to patient safety. The PPA also expressed concerns with the overall concept behind the law and the regulations. The Board acknowledges these concerns, however, promulgation of these regulations are mandated by the General Assembly under the CDRPA and the Board believes the final-form regulations make the program as safe as possible within the statutory framework. The PSOH commented generally that it supports the proposed regulations and believes all necessary safeguards for quality assurance have been incorporated.

The HPLC commented that the proposed rulemaking was published approximately 2 years and 7 months past the 90 days from the effective date of the CDRPA. The Board

acknowledges that the rulemaking has taken much longer than anticipated by the General Assembly to complete.

IRRC asked how the Board will make the availability of the Program known to the citizens of the Commonwealth, and whether the Board has considered listing the pharmacies that participate in the Program on its website. The Board will add a notice to the public regarding the availability of the Program and, when available, a list of the pharmacies that participate in the Program on its website. Further, the Board believes that participating pharmacies also will advertise the availability of the Program at the pharmacy.

Further, IRRC noted that the Regulatory Analysis Form submitted with the proposed rulemaking states there will be no costs or savings to the regulated community. The comment from IRRC further references the comments from the PPA, which indicate there would be costs to participating pharmacies to comply with the regulation associated with additional manpower, storage facilities and paperwork, as well as possibly additional liability insurance costs. The Pennsylvania Medical Society expressed similar concerns about the potential increased risk of professional liability exposure to pharmacists. The existence of these costs, if any, would depend on several unknown and unknowable factors including how many pharmacies participate in the program, how many cancer drugs are donated, and whether participating pharmacies have existing space and manpower to run the Program. If there are relatively few drugs donated, the pharmacy may not have additional costs in the form of manpower or space. Further, the insurance market would determine whether additional liability insurance is required, and if so, how much. The increase in additional liability insurance may depend on how many cancer drugs are donated and dispensed, which translates into exposure risk. Additionally, given the immunity section in the CDRPA (62 P.S. § 2926), there may not be an increase in liability insurance premiums. In other words, whether there would be increased costs would be speculative at best, and the determination of those costs, if any, is impossible for the Board to estimate with any meaningful figures.

IRRC also asked the Board to quantify the potential savings an eligible cancer patient could realize by obtaining medication through the Program. According to the American Cancer Society, the average cost of a 30-day cancer drug prescription was more than $1,600 in 2006, and it is even higher today. Many cancer drugs cost more than drugs for other illnesses. Some of the newer cancer treatments can cost as much as $10,000 for a month's supply. Estimating the potential savings to eligible cancer patients would also depend on several unknowable factors. First, cost savings would depend on how many eligible cancer patients participate in the Program. Second, savings to a specific patient would depend on how much of a patient's prescribed medication is available through the Program. It seems unlikely that *all* of the patient's cancer drug regimen would be available. Also, the amount available may vary from month to month, and the patient's drug regimen may vary, depending upon the patient's therapeutic responses to previously prescribed medications and the advancement of the disease. Finally, cancer drugs vary greatly in cost depending on the particular drug or combination of drugs involved.

For all of these reasons, the Board finds that it is unable to estimate the possible costs to participating pharmacies or the possible savings to eligible cancer patients with any meaningful figures.

Purpose

With regard to the language in § 27.501 (relating to purpose), the HPLC suggested that the word "Pennsylvania" be added before the words "residents who are indigent." The Board agrees and has made this amendment to be consistent with § 27.506(b) (relating to patient eligibility), specifically pertaining to financial eligibility for the Program, and in response to the HPLC recommendation.

Definitions

The Board received several comments regarding the definition of "original sealed and tamper-evident unit dose packaging." First, the HPLC recommended adding the word "unopened" before the word "sealed" to align with the statutory language. The Board has made that amendment. Next, IRRC noted that the definition implies that injectable, topical and aerosol medications would be considered oral medications and available as single unit doses. The HPLC, the PPA and the FDA provided similar comments. The Board has amended the definition as suggested by the HPLC and the FDA to address these comments. In response to the concerns regarding whether injectables, topical and aerosols can be packaged in unit doses, the Board is aware that unit dose packaging of solid oral medications is the most common type of unit dose packaging, but that there are existing unit dose packaging systems not only for oral solids, but also for liquids such as ampules, vials and pre-filled syringes, and for topical ointments and creams. Although perhaps less common, companies are developing unit dose spray (aerosol) drug delivery systems.

Regarding the terminology "tamper-evident", the PPA noted that the term is commonly used for over-the-counter drugs, and not for prescription drugs which are the subject of this rulemaking. The PPA suggested that including the term in the final-form rulemaking may very well confuse practitioners. Further, as the FDA indicates, the tamper-evident feature may be added to the package after adulteration, and the receiving pharmacist would not be aware of it. The Board agrees with these concerns, but declines to delete "tamper-evident" because it would be inconsistent with the terminology used in section 4 of the CDRPA (62 P.S. § 2924). In addition, the FDA raised no concerns about the use of the terminology "tamper-evident" as it applies to this rulemaking, only that it would be difficult, if not impossible, for a pharmacist to ensure the safety of recycled drugs even if they were in "tamper-evident" packaging.

Additionally, the HPLC and the FDA pointed out that the FDA "registers" repackagers, rather than "licensing" them. Accordingly, the word "licensed" was replaced with the word "registered" in the definition of "original unopened, sealed and tamper-evident unit dose packaging," as amended in the final-form rulemaking. Finally, the Board amended the definition because it essentially defined the term with the same term. That is, as defined in the proposed rulemaking "original unopened, sealed and tamper-evident unit dose packaging" must be in the manufacturer's or repackager's unopened original tamper-evident packaging. Instead, the final-

form rulemaking has been amended to clarify that an "original unopened, sealed and tamper-evident unit dose packaging" is one that has been visually inspected by a licensed pharmacist to determine that the drug appears to be unbreached.

Participation in the Cancer Drug Repository Program

In § 27.503(b) (relating to participation in the Cancer Drug Repository Program), paragraphs (4) and (5) were reversed for clarity because the Board agreed that it simply makes more sense to first require the certification by a pharmacist and *then* require that pharmacist's information. Also, the HPLC recommended changing "certification *of* a pharmacist" to "certification *by* a pharmacist." This recommendation also was accepted.

In subsection (c), "donated *prescription* drugs" was changed to "donated *cancer* drugs" to conform to the defined term "cancer drug" as recommended by HPLC and IRRC.

In subsection (d), the heading was changed from "Donations of cancer drugs *and supplies*" to "Donations of cancer drugs." As IRRC and HPLC noted, the CDRPA does not provide for the donation of supplies. Similar changes were made throughout subsection (d) and other sections of the final-form regulation. Other comments asking for clarification of what constituted eligible supplies have been made moot by this change.

Regarding subsection (d)(1), as IRRC notes, the CDRPA requires donations from a closed drug delivery system. The definition of "closed drug delivery system" in the CDRPA is limited to 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.*" (Emphasis added) Accordingly, the words "An individual who is 18 years old or older or a" were deleted. This change is made throughout the regulation and addresses some of the FDA's and PPA's noted safety concerns about accepting donations from individuals.

IRRC also commented that the forms that will be used to implement the Program be amended to ensure consistency with the act and these regulations. The Board has updated the forms accordingly.

Drugs

IRRC asked how § 27.504(a)(2) (relating to drugs) comports with section 5(a)(9)(xi) of the Pharmacy Act (63 P.S. § 390-5(a)(9)(xi)) which provides that "[t]he acceptance back and redistribution of any unused drug, or a part thereof, after it has left the premises of any pharmacy, whether issued by mistake or otherwise, unless it is in the original sealed container" is an act of "grossly unprofessional conduct of a pharmacist". This is a common problem with a stand-alone act is enacted which appears to conflict with an existing statute, rather than amending the existing statute. In this instance, section 4 (1) of the CDRPA allows the acceptance of donated cancer drugs in single-unit doses if the "outside packaging is opened but the single-unit-dose packaging is unopened." Section 27.504(2) is in accord with the language of the CDRPA. Principles of statutory construction require that the Board construe the two statutes (the act and the CDRPA) together, if possible, and where they cannot be reconciled that the

statute enacted later prevails. Therefore, the Board construes this provision as meaning that the "single-unit dose packaging" is considered the original sealed container as it pertains to drugs that are part of the Cancer Drug Repository Program for purposes of section 5(a)(9)(xi) of the Pharmacy Act.

The FDA noted concerns that "even if packaged in a way mandated by § 27.504, the receiving pharmacist may not be able to tell if the product or package was further manipulated...." Evident in the comments of the FDA are concerns about donated drugs coming from individuals outside the closed drug delivery system. Given that the language of subsection (a)(1) and (2) essentially tracks that of the CDRPA, and the final-form regulation allows donations only from closed drug delivery systems, the Board feels that the FDA's concerns largely are addressed.

Repositories

Regarding § 27.505(b) (relating to repositories), IRRC noted that the subsection contains language including only a portion of section 5 of the CDRPA. Accordingly, the remaining language from section 5 of the CDRPA ("The cancer 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.") was added for consistency. In addition, the Board added "health care facility" to the list to be consistent with the definition of "closed drug delivery system."

Also, regarding subsection (b), the requirement that the participating pharmacy "inspect all cancer drugs prior to dispensing to determine if they are adulterated or misbranded" was changed to require the pharmacy to "visually" inspect the drugs "in such a manner as to be able to reasonably determine" if they are adulterated or misbranded. The PPA noted concerns that a pharmacist could check for obvious signs of adulteration or misbranding, but that a pharmacist could not establish conclusively whether the drug is adulterated or misbranded. The FDA made similar comments that the receiving pharmacist may not be able to tell if the package was manipulated. The Board agrees, but would add that the drugs will remain in the closed drug delivery system, so the likelihood of intentional adulteration or misbranding is minimized, and the requirements for proper storage, and destruction of drugs within 6 months prior to the expiration date will minimize inadvertent adulteration or misbranding. The visual inspection adds to the minimization of adulterated or misbranded drugs. The Board does not believe that the drafters of the legislation intended to require an absolute determination, which as the FDA points out, is nearly impossible and would require "complex laboratory analyses" of every donated cancer drug. A similar change has been made to subsection (e)(4). Subsections (e)(4) and (5) serve to inform the patient that a visual inspection of the donated cancer drug has been conducted and that nobody can guarantee the safety of the drug.

The PPA recommended addition of "in a manner in compliance with all applicable Federal and State laws" to subsection (c) regarding destruction or disposition of donated cancer drugs that are not accepted into the program for dispensing. The PPA recommended this to reflect that the national attention on proper disposal or destruction inevitably will result in

forthcoming legislation. The Board finds this recommendation reasonable, and has amended the final-form rulemaking accordingly.

The HPLC requested an explanation as to how the Board will make certain repackaging fees (as addressed in subsection (g)) are reasonable. The Board believes that the limitation on the fee which is tied to the Department of Public Welfare's method of payment for pharmaceutical services in 55 Pa. Code § 1121.55 (relating to method of payment) sets a reasonable limit on what handling fees may be charged. The participating pharmacy certainly is permitted to charge less than the fee limit.

Patient eligibility

Section 27.506 (relating to patient eligibility) contains conditions of medical, insurance, and financial eligibility to receive donated cancer drugs under the Program. In the proposed regulation, subsection (a) contained requirements that the patient is diagnosed with cancer, does not possess adequate prescription drug coverage, and is not eligible for state Medical Assistance prescription drug coverage.

The HPLC noted that several commentators have asked what type of proof would be necessary to satisfy these criteria. The PPA and PMS submitted questions such as whether the pharmacist will require documentation of the cancer diagnosis. After several discussions regarding this particular section, the Board has determined that to require a pharmacy or pharmacist who volunteers to participate in the program to research a patient's diagnosis to determine eligibility is well beyond what should be required. Several other states with similar eligibility requirements for similar programs require the patient to sign a certification that they meet each requirement. Consequently, the final-form rulemaking has been changed to require that the patient certify that the patient meets the eligibility requirements for participation in the Program.

Subsection (b) establishes the criteria for financial eligibility. Subsection (b)(1) states that a Pennsylvania resident who meets the eligibility requirements (above) is financially eligible as an "indigent patient" as long as he or she meets the income standards in subsection (b)(2).

Subsection (b)(2) sets the income limits for eligibility and bases them upon the family income not exceeding 350% of the current Department of Health and Human Services Federal Poverty Income Guidelines for the appropriate family size. The current income limits are provided in Appendix A of the regulation. The proposed regulation then notes that revisions to the income limits will be published as a notice in the *Pennsylvania Bulletin.* IRRC has questioned whether the Board has considered publishing the guidelines on an annual basis rather than only when the guidelines change. The Board notes that the Department of Health and Human Services updates the income limits annually and publishes a notice of the revised limits in the Federal Register (see 78 FR 5182, January 24, 2013), so the Board had already anticipated that there would be an annual update. Alternatively, IRRC notes, the income guidelines could be posted on the Board's website. The Board has given consideration to IRRC's comments and agrees that the Board's website will be a more efficient and accessible place to post any changes. Accordingly, the final-form rulemaking was amended to make it clear that revisions to the

income limits will be posted on the Board's website. In addition, Annex A has been amended to reflect the most recent Poverty Income Guidelines as established by the United States Department of Health and Human Services.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions. The 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. There may be costs to participating pharmacies associated with manpower, storage facilities for donated cancer drugs, paperwork requirements, and increased liability insurance premiums. There may be substantial savings to indigent cancer patients who participate in the Program and will be able to obtain at least a portion of their cancer drugs at no cost.

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 the notice of proposed rulemaking, published at 41 Pa.B. 1337, to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final form rulemaking, the Board has considered all comments received from IRRC, HPLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act, on _____ __, 2013, the final form rulemaking was deemed approved by the HPLC and the SCP/PLC. Under section 5.1(3) of the Regulatory Review Act, IRRC met on _____ __, 2013 and approved the final form rulemaking.

Additional Information

Persons who require additional information about the final form rulemaking should submit inquiries to Board Counsel, State Board of Pharmacy, by mail to P.O. Box 2649, Harrisburg, PA 17105-2649, by telephone at (717) 783-7156, or by e-mail at st-pharmacy@state.pa.us.

Findings

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) and regulations promulgated thereunder, 1 Pa. Code §§

7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) The amendments to this final-form rulemaking do not enlarge the scope of proposed rulemaking published at 41 Pa.B. 1337.

(4) The final form rulemaking adopted by this order is necessary and appropriate for the administration of the Cancer Drug Repository Program Act.

Order

The Board, acting under its authorizing statute, orders that:

(a) The regulations of the Board at 49 Pa. Code Chapter 27 are amended, by adding §§ 27.501-27.506 as set forth in Annex A.

(b) The Board shall submit this order and Annex A to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) The final form rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.

Edward J. Bechtel, RPh
Chairperson
State Board of Pharmacy

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 PENNSYLVANIA 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 UNOPENED, sealed and tamper-evident unit dose packaging – Single unit dose packaging of ~~oral medications~~ A DRUG PRODUCT from a manufacturer or a repackager ~~licensed~~ REGISTERED with the Federal Food and Drug Administration, or from a licensed PENNSYLVANIA pharmacy, THAT HAS BEEN VISUALLY INSPECTED BY A LICENSED

PHARMACIST EMPLOYED BY OR UNDER CONTRACT WITH THE PARTICIPATING PHARMACY TO DETERMINE THAT THE DRUG APPEARS TO BE UNBREACHED, and includes ORAL MEDICATIONS, 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~~ BY a licensed pharmacist who is employed by or under contract with the pharmacy that the pharmacy meets the eligibility requirements for participation in the program under subsection (c).

(5) THE NAME AND TELEPHONE NUMBER OF THE LICENSED PHARMACIST EMPLOYED BY OR UNDER CONTRACT WITH THE PHARMACY WHO MADE THE CERTIFICATION REQUIRED BY PARAGRAPH (4).

(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~~ CANCER 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~~ A pharmacy, ~~medical~~ HEALTH CARE 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 ORIGINAL 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 shall VISUALLY inspect all cancer drugs prior to dispensing ~~to~~ IN SUCH A MANNER AS TO BE ABLE TO REASONABLY 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. THE CANCER DRUGS MAY BE DISTRIBUTED TO ANOTHER PARTICIPATING PHYSICIAN'S

OFFICE, PHARMACY, HOSPITAL, HEALTH CARE FACILITY OR HEALTH CLINIC FOR DISPENSING BY A PHARMACIST AS ALLOWED BY FEDERAL OR STATE LAW.

(c) *Disposition.* The approved participating pharmacy repository shall destroy or dispose of donated drugs IN A MANNER IN COMPLIANCE WITH ALL APPLICABLE FEDERAL AND STATE LAWS 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 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 UNOPENED, 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 UNOPENED, sealed and tamper-evident packaging to be restocked and redistributed.

(4) A visual inspection has been conducted by the pharmacist ~~to ensure~~ IN SUCH A MANNER AS TO BE ABLE TO REASONABLY DETERMINE that the drug has not expired, has not been adulterated or misbranded, and is in its original unopened, SEALED AND TAMPER-EVIDENT 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.* All 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 must maintain any records required by 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 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~~ CERTIFY THAT THE PATIENT MEETS 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.~~ POSTED ON THE BOARD'S WEBSITE.

(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~~

CURRENT INCOME LEVELS FOR THE CANCER DRUG

REPOSITORY PROGRAM

FAMILY SIZE	2013ANNUAL INCOME LIMIT
1	$40,215
2	$54,285
3	$68,355
4	$82,425
5	$96,425
6	$110,565
7	$124,635
8	$137,760
EACH ADDITIONAL PERSON	$14,070

COMMENTATORS LIST
REGULATION NO. 16A-5423

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
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April 8, 2013

The Honorable Silvan B. Lutkewitte, III, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Final Regulation
State Board of Pharmacy
16A-5423: CANCER DRUG REPOSITORY PROGRAM

Dear Chairman Lutkewitte:

Enclosed is a copy of a final rulemaking package of the State Board of Pharmacy pertaining to Cancer Drug Repository Program.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

Edward J. Bechtel, RPh, Chairperson
State Board of Pharmacy

EJB/KEM:rs

Enclosure

cc: Katie True, Commissioner
Bureau of Professional and Occupational Affairs
Rebecca Oyler, Director of Policy, Department of State
Steven V. Turner, Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Kerry E. Maloney, Counsel
State Board of Pharmacy
State Board of Pharmacy

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-5423
SUBJECT:	CANCER DRUG REPOSITORY PROGRAM
AGENCY:	DEPARTMENT OF STATE STATE BOARD OF PHARMACY

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

RECEIVED
APR 08 2013
INDEPENDENT REGULATORY REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
4/8/13	Michele Warren	MAJORITY CHAIRMAN Julie Harhart
		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
4/8/13	Mary Walmer	MAJORITY CHAIRMAN Robt. M. Tomlinson
4/8/13	K Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

April 5, 2013