RULES AND REGULATIONS

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Cancer Drug Repository Program

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

Effective Date

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

Statutory Authority

This final-form 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 Purpose

The CDRPA 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 the 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 (PMS); the Pennsylvania Society of Oncology and Hematology (PSOH); the United States 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 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 is 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 supported the proposed rulemaking and believes the 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 deadline in the CDRPA—90 days from the effective date of the CDRPA. The Board acknowledges that the rulemaking process has taken much longer to complete than anticipated by the General Assembly.

IRRC asked how the Board will make the availability of the Program known to the citizens of this Commonwealth, and whether the Board has considered listing the pharmacies that participate in the Program on its web site. 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 the Board's web site. Further, the Board believes that participating pharmacies also will advertise the availability of the Program at the pharmacies.

Further, IRRC noted that the Regulatory Analysis Form submitted with the proposed rulemaking stated there will not be costs or savings to the regulated community. A comment from IRRC further referenced the comments from the PPA, which indicated there would be costs to participating pharmacies to comply with the regulations associated with additional manpower, storage facilities and paperwork, as well as possibly additional liability insurance costs. The PMS 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 section 6 of the CDRPA (62 P. S. § 2926), regarding immunity, 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 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. Cost savings would depend on how many eligible cancer patients participate in the Program. 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. Cancer drugs vary greatly in cost depending on the particular drug or combination of drugs involved.

For 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 meaningful figures.

Purpose

In regard to § 27.501 (relating to purpose), the HPLC suggested that "Pennsylvania" be added before "residents who are indigent." The Board agrees and 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 proposed definition of "original sealed and tamper-evident unit dose packaging." The HPLC recommended adding "unopened" before word "sealed" to align with statutory language. The Board made that amendment. 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 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 and that there are existing unit dose packaging systems not only for oral solids, but also for liquids such as ampules, vials and prefilled 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, not for prescription drugs which are the subject of the rulemaking. The PPA suggested that including the term in the final-form rulemaking may confuse practitioners. Further, as the FDA indicated, 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 declined to delete "tamper-evident" because it would be inconsistent with the terminology in section 4 of the CDRPA (62 P. S. § 2924). In addition, the FDA did not raise concerns about the use of the terminology "tamper-evident" as it applies to this final-form 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.

The HPLC and the FDA pointed out that the FDA "registers" repackagers, rather than "licensing" them. Accordingly, "licensed" was replaced with "registered" in the definition of "original unopened, sealed and tamper-evident unit dose packaging" as amended in the final-form rulemaking. 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 packaging appears to be unbreached and undamaged.

Participation in the Program

Section 27.503(b)(4) and (5) (relating to participation in the Cancer Drug Repository Program) has been 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. 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 the HPLC and IRRC.

The heading of subsection (d) has been changed from "donations of cancer drugs and supplies" to "donations of cancer drugs." As IRRC and the 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 rulemaking. Other comments asking for clarification of what constituted eligible supplies have been made moot by this change.

Regarding subsection (d)(1), as IRRC noted, 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, "An individual who is 18 years old or older or a" has been deleted. This change is made throughout the final-form rulemaking and addresses some of the FDA's and the 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 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 when 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 CDRPA. Principles of statutory construction require that the Board construe the two statutes (the act and the CDRPA) together, if possible, and when they cannot be reconciled 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 Program for purposes of section 5(a)(9)(xi) of the 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

subsection (a)(1) and (2) essentially tracks that of the CDRPA, and the final-form regulations allow donations only from closed drug delivery systems, the Board feels that the FDA's concerns largely are addressed.

Repositories

IRRC noted that § 27.505(b) (relating to repositories) contains language including only a portion of section 5 of the CDRPA (62 P. S. § 2925). 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."

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 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, and adds 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 was made to subsection (e)(4). Subsection (e)(4) and (5) serves 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 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 contains conditions of medical, insurance and financial eligibility to receive donated cancer drugs under the Program. Proposed 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 asked what type of proof would be necessary to satisfy these criteria. The PPA and the PMS submitted questions such as whether the pharmacist will require documentation of the cancer diagnosis. After several discussions regarding this particular section, the Board 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 he meets each requirement. Consequently, the final-form rulemaking has been revised to require that the patient certify that he meets the eligibility requirements for participation in the Program, as it is done in many other states.

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

Final-form subsection (b)(2) sets the income limits for eligibility and bases them upon the family income for the prior year not exceeding 350% of the prior year's United States Department of Health and Human Services Federal Poverty Income Guidelines for the appropriate family size. The Board originally proposed that current income be the guide. IRRC pointed out that it would be difficult to calculate a person's current year income before the end of the year. For ease of administration, the Board concluded that financial eligibility should be based on family income for the prior year, as compared to 350% of the prior year's Federal Poverty Income Guidelines. The proposed subsection noted that revisions to the income limits will be published as a notice in the *Pennsylvania Bulletin*. IRRC questioned whether the Board considered publishing the guidelines on an annual basis rather than only when the guidelines change. Alternatively, IRRC noted, the income guidelines could be posted on the Board's web site. The Board notes that the United States 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. The Board has given consideration to IRRC's comments and agreed to adopt both suggestions. Accordingly, the final-form rulemaking was amended to make it clear that revisions to the income limits will be published as a notice in the *Pennsylvania Bulletin* and posted on the Board's web site at least once a year as the Federal guidelines change. In addition, proposed Appendix A has not been adopted.

Fiscal Impact and Paperwork Requirements

The final-form rulemaking will not have adverse fiscal impact on the Commonwealth or its political subdivisions. The final-form rulemaking will impose additional paperwork requirements upon the Board in the form of the processing of applications for participation in the Program. The final-form rulemaking also contains recordkeeping requirements for the regulated community. There may be costs to participating pharmacies associ-

ated 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.

Disapproval by IRRC

As stated in its disapproval order of June 14, 2013, IRRC disapproved the final rulemaking for two reasons. The first reason IRRC disapproved the final rulemaking was because it required a patient to certify that he meets the eligibility criteria of the Program and IRRC was concerned that the self-certification requirement, without any additional requirement for independent verification and review, could create a liability issue under section 1128b of the Social Security Act (42 U.S.C.A. § 1320a-7b), regarding criminal penalties for acts involving Federal health care programs, for pharmacies wishing to participate in the Program. The Board reviewed this concern, but did not amend the revised final-form rulemaking in response, noting that the Program does not meet the statutory definition of "Federal health care program" subject to the cited section and that self-certification of eligibility by the patient would make the patient liable for providing false information, not the pharmacy.

The second reason stated for disapproval was that IRRC concluded that § 27.506(b) lacked clarity with regard to the income limits. IRRC recommended the Board consider one of two alternatives. IRRC suggests that if Appendix A is retained, that changes be made by means of publication of a notice in the *Pennsylvania Bulletin* annually and whenever changes are made, and that the changes also be posted on the Board's web site. In the alternative, IRRC suggested that Appendix A be deleted and that the formula in § 27.506(b)(2) be relied upon. IRRC also noted a concern that Appendix A references current income levels instead of prior year income levels. This was a concern about administering this provision because it would be very difficult, if not impossible, to accurately calculate a current annual income prior to the end of that year. As a result, the Board determined it was reasonable to incorporate all of IRRC's suggestions and revised this section accordingly.

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 IRRC and the Chairpersons of the HPLC and the SCP/PLC for review and comment.

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 considered comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on April 24, 2013, the final-form rulemaking was approved by the HPLC. On May 15, 2013, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on May 16, 2013, and disapproved the final-form rulemaking. IRRC issued its disapproval order on June 14, 2013.

The Board delivered the revised final-form rulemaking, together with a copy of IRRC's disapproval order and the supporting report required under section 7(c) of the Regulatory Review Act (71 P. S. § 745.7(c)) to IRRC, the HPLC and the SCP/PLC on July 24, 2013. Under section 7(c.1) of the Regulatory Review Act, IRRC met on August 22, 2013, and approved the final-form rulemaking. Under section 7(d) of the Regulatory Review Act, the final-form rulemaking was deemed approved by the HPLC and by the SCP/PLC on September 5, 2013.

Additional Information

Persons who require additional information about the final-form rulemaking should submit inquiries to Kerry Maloney, Board Counsel, State Board of Pharmacy, P.O. Box 2649, Harrisburg, PA 17105-2649, (717) 783-7156, 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) (45 P. S. §§ 1201 and 1202) 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 CDRPA.

Order

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

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

(*Editor's Note*: Chapter 27, Appendix A included in the proposed rulemaking published at 41 Pa.B. 1337 has not been adopted.)

(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

(*Editor's Note*: See 43 Pa.B. 7060 (November 30, 2013) for a notice relating to this final-form rulemaking.)

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 43 Pa.B. 5435 (September 7, 2013).)

Fiscal Note: Fiscal Note 16A-5423 remains valid for the final adoption of the subject regulations.

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 a drug product from a manufacturer or a repackager 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 who has determined that the packaging appears to be unbreached and undamaged, and includes oral medications, injectables, topicals and aerosols.

§ 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) A description of all pharmacy services provided and the location and manner in which those services are provided.

(4) A certification 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 Cancer Drug Repository 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 under paragraph (4).

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

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

(2) Delegates to a licensed pharmacist employed by or under contract with the pharmacy the responsibility to receive delivery of donated cancer drugs at the designated delivery area in the pharmacy.

(3) 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.*

(1) A pharmacy, health care facility, drug manufacturer or wholesale drug distributor may donate legally obtained cancer drugs to an approved participating pharmacy if the drugs 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 must be accompanied by a cancer drug repository donor form on a form provided by the Board that:

(i) Is signed by the entity's authorized representative.

(ii) States that to the best of the donor's knowledge the donated drug has been properly stored and that the drug 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 in 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 laws relating to the storage, distribution, dispensing, disposal and destruction of cancer drugs and visually inspect all cancer drugs prior to dispensing in 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 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 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 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 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 in 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 being dispensed or administered, and that the pharmacist has determined that the drug appears to be safe to dispense or administer based on the accuracy of the donor's form submitted with the donated drug 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.

(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 under the Cancer Drug Repository Program.

§ 27.506. Patient eligibility.

(a) *Conditions of eligibility.* To be eligible for the Cancer Drug Repository Program, a patient shall 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 the prior year's family income not to exceed 350% of the prior year's Department of Health and Human Services Federal Poverty Income Guidelines for the appropriate family size. The income limits will be published as a notice in the *Pennsylvania Bulletin* and posted on the Board's web site at least once a year as the Federal Poverty Income Guidelines change.

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

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