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INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

May 11, 2011

Richard R. Smiga, R.Ph., Chair
State Board of Pharmacy
2601 North 3rd Street
Harrisburg, PA 17110

Re: Regulation #16A-5423 (IRRC #2889)
State Board of Pharmacy
Cancer Drug Repository Program

Dear Mr. Smiga:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact me.

Sincerely,

Kim Kaufman
Executive Director
sfh
Enclosure
cc: Honorable Robert M. Tomlinson, Majority Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable Julie Harhart, Majority Chairman, House Professional Licensure Committee
Honorable Harry A. Readshaw, Minority Chairman, House Professional Licensure Committee
Honorable Carol Aichele, Secretary, Department of State
Robert A. Mulle, Esq., Office of Attorney General
Andrew Clark, Esq., Office of General Counsel

Comments of the Independent Regulatory Review Commission

State Board of Pharmacy Regulation #16A-5423 (IRRC #2889)

Cancer Drug Repository Program

May 11, 2011

We submit for your consideration the following comments on the proposed rulemaking published in the March 12, 2011 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the State Board of Pharmacy (Board) to respond to all comments received from us or any other source.

1. Implementation Procedures.

Act 14 of 2008, known and cited as the Cancer Drug Repository Program Act (62 P.S. §§ 2921-2927) (Act) created the Cancer Drug Repository Program (Program). Section 3 of the Act (62 P.S. § 2923) requires the Board to establish a Program, "through which unused cancer drugs may be dispensed to cancer patients by pharmacies approved by the board for the purpose of dispensing unused cancer drugs to residents who are indigent." As directed by Section 7 of the Act (62 P.S. § 2927), the Board is promulgating regulations to carry out the purposes of the Act.

In order for the citizens of this Commonwealth to take advantage of the Program, they must be aware of it. How will the Board make the availability of this Program known to the citizens of this Commonwealth? Has the Board considered listing the pharmacies that participate in the Program on its website?

2. Economic or fiscal impact of the regulation.

The Regulatory Analysis Form submitted with this proposed rulemaking states that there will be no costs or savings to the regulated community, local government or state government. The Pennsylvania Pharmacists Association disagrees with this statement and contends that the costs to pharmacies will be significant and the result will be few pharmacies participating in the Program. Included in those costs would be additional manpower, storage

facilities, paperwork and the possible need for additional liability insurance. We ask the Board to quantify the actual costs a pharmacy that seeks to participate in the Program would incur.

In addition, we ask the Board to quantify the potential savings a cancer patient that meets all of the criteria of this regulation could realize by obtaining his or her cancer medication through the Program.

3. Section 27.502. Definitions. – Clarity.

We have several questions concerning the definition of "original sealed and tamper-evident unit dose packaging." The definition implies that injectable, topical and aerosol medication would be considered oral medications. How do these medications qualify as oral medications? Are these types of medicines available as single unit doses? The final-form regulation should be clarified to address these questions.

4. Section 27.503. Participation in the Cancer Drug Repository Program. – Consistency with intent of the General Assembly; Clarity.

We have four concerns with this section. First, Section 7(3) of the Act (62 P.S. § 2927(3)) requires the Board to promulgate regulations that shall include, "Necessary forms for administration of the program, including forms for use by entities permitted to accept, distribute or dispense cancer drugs under the program." The Board has submitted copies of five forms that will be used to administer the Program with this regulatory package. The title of each form is listed below:

- Application for Prescription Drug Repository;
- Prescription Drug Repository Program Donor Form;
- Cancer Drug Repository Program Donation, Transfer and Destruction Record;
- Cancer Drug Repository Program Recipient Record; and
- Cancer Drug Repository Program Notice of Participation or Withdrawal.

While not a part of the actual regulation, we recommend that the titles for the first two forms be amended by deleting the term "prescription drug" and replacing it with "cancer drug." This would ensure consistency with Section 7(3) of the Act. We also suggest that all of the forms be reviewed to ensure consistency with this underlying principle of the Act.

Second, Subsection (c) establishes eligibility requirements for pharmacies that want to participate in the Program. Subsection (c)(2) includes a reference to donated "prescription drugs or medical supplies." To be consistent with the intent of the Act, we recommend that the reference to "prescription drugs" be replaced with "cancer drugs."

Third, Subsection (d) pertains to donations of cancer drugs and supplies. This subsection of the regulation is the only subsection that makes reference to "supplies." To be consistent with the Act and the rest of the regulation, we recommend that the term "supplies" be deleted.

Fourth, Subsection (d)(1) would allow "an individual who is 18 years old or older or a pharmacy, medical facility, drug manufacturer or wholesale drug distributor" to donate cancer drugs to the Program. Section 4 of the Act (62 P.S. § 2924) states that entities that are part of a "closed drug delivery system" may return unused cancer drugs to pharmacies participating in the Program. We note that a "closed drug delivery system" is defined by Section of the Act (62 P.S. § 2922) as, "A system in which the actual control of a unit dose of medication is maintained by a health care facility, health clinic, hospital, pharmacy or physician's office rather than an individual." We ask the Board to explain its statutory authority for allowing any person or entity that does not fall under the definition of a "closed drug delivery system" to donate cancer drugs to the Program. We also ask the Board to ensure that the final-form regulation and any forms developed for the administration of the Program reflect the intent of the Act by ensuring that donated cancer drugs come from a closed drug delivery system.

5. Section 27.504. Drugs. – Possible conflict with or duplication of statutes or existing regulations; Clarity.

Subsection (a) pertains to cancer drugs that may be accepted by a pharmacy participating in the Program. We have two concerns. First, Subsection (a)(1) includes the phrase "original ***unopened***, sealed and tamper-evident unit dose packaging." (Emphasis added.) We question why the term "unopened" was included in this phrase. We note that Section 27.502, pertaining to definitions, defines the term "original sealed and tamper-evident unit dose packaging."

Second, Subsection (a)(2) would allow the donation of cancer drugs in single unit doses, "when the outside packaging is opened but the single-unit-dose packaging is unopened." We ask the Board to explain how this provision comports with Section 5(a)(9)(xi) of the Pharmacy Act (63 P.S. § 390-5(a)(9(xi)), which identifies the following action as "grossly unprofessional conduct of a pharmacist":

> The acceptance back and redistribution of any unused drug, or a part thereof, after it has left the premises of any pharmacy, whether issued by a mistake or otherwise, unless it is in the ***original sealed container*** with the name, lot number and expiration date on the original intact manufacturer's label. (Emphasis added.)

6. Section 27.505. Repositories. – Consistency with intent of the General Assembly; Clarity.

This section pertains to the distribution, destruction and disposition of cancer drugs donated to the Program. We have two concerns. First, Subsection (b) states, in part, the following: "The cancer drugs shall only be dispensed by a licensed pharmacist according to State law pursuant to a prescription issued by a prescribing practitioner." This language comes directly from Section 5 of the Act (62 P.S. § 2925). However, Section 5 also includes the following language: "The cancer drugs may be distributed to another participating physician's office, pharmacy, hospital or health clinic for dispensing by a pharmacy as allowed by Federal or State law." We are concerned that the additional statutory language is not included in the regulation. We suggest that the final-form regulation include language that reflects the other method of distributing cancer drugs.

Second, as noted by PPA, Subsection (f)(3)(vii) includes the phrase, "if applicable." What is the need for this phrase? We recommend that it be deleted.

7. Section 27.506. Patient eligibility. – Implementation procedures; clarity.

Subsection (a) establishes three criteria for eligibility for the Program. The criteria are: the patient is diagnosed with cancer; 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; 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. Several commentators have asked what type of proof would be necessary to satisfy these criteria. We recommend that the final-form regulation include the type of documentation that would be acceptable to meet the criteria set forth in Subsection (a).

Subsection (b) establishes the criteria for financial eligibility for the Program. Under Subsection (b)(2), the income limits for eligibility for the Program are based upon family income not to exceed 350% of the current Department of Health and Human Services Federal Poverty Income Guidelines. The current income limits for eligibility for the Program are in Appendix A of the regulation and any revisions to the income limits will be published as a notice in the Pennsylvania Bulletin. Has the Board considered publishing the income guidelines on an annual basis instead of only when the guidelines change? We believe this approach would make it easier for the regulated community to locate what the income guidelines are. An alternative to this approach would be listing the income guidelines on the Board's website.

Facsimile Cover Sheet

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INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

To: Tom Blackburn
Cynthia Montgomery
Agency: Department of State
Licensing Boards and Commissions
Phone: 3-7200
3-3394 (Cynthia Montgomery)
Fax: 7-0251
Date: 5/11/11
Pages: 6

Comments: We are submitting the Independent Regulatory Review Commission's comments on the State Board of Pharmacy regulation #16A-5423 (IRRC #2889). Upon receipt, please sign below and return to me immediately at our fax number 783-2664. We have sent the original through interdepartmental mail. You should expect delivery in a few days. Thank you.

Accepted by: _____ **Date:** 5-11-11

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