

**INDEPENDENT REGULATORY REVIEW COMMISSION
DISAPPROVAL ORDER**

Commissioners Voting:

Public Meeting Held May 16, 2013

Silvan B. Lutkewitte, III, Chairman
George D. Bedwick, Vice Chairman
Lawrence J. Tabas, Esq.
Dennis A. Watson, Esq., dissenting

Order Issued June 14, 2013
Regulation No. 16A-5423 (#2889)
State Board of Pharmacy
Cancer Drug Repository Program

On March 2, 2011, the Independent Regulatory Review Commission (Commission) received this proposed regulation from the State Board of Pharmacy (Board). This rulemaking amends 49 Pa. Code Chapter 27 by adding §§ 27.501-27.506. The proposed regulation was published in the March 12, 2011 *Pennsylvania Bulletin* with a 30-day public comment period. The final-form regulation was submitted to the Commission on April 8, 2013.

This final-form rulemaking establishes the Cancer Drug Repository Program (Program) as required by the Cancer Drug Repository Program Act of 2008 (Act). 62 P.S. §§ 2921-2927. The rulemaking is disapproved for two reasons. First, new language was added to § 27.506(a) that requires a patient to certify that the patient meets the eligibility criteria of the Program. This self-certification requirement, without any additional requirement for independent verification and review, could create a liability issue under the federal Anti-Kickback Statute for pharmacies wishing to participate in the Program. *See* 42 U.S.C. § 1320a-7b. We question whether the Board considered the federal law and any applicable safe harbors when it amended the final-form regulation to require a patient to self-certify the patient's own eligibility. This increased risk of liability may result in pharmacies choosing not to participate in the Program. We do not believe that limiting the number of pharmacies that are willing to participate in the Program is reasonable or consistent with the intent of the General Assembly when it passed the Act. (71 P.S. §§745.5b(a) and(b)(3)).

If the Board decides to return this rulemaking with changes, as provided by Section 7(c) of the Regulatory Review Act (71 P.S. § 745.7(c)), we ask the Board to work with representatives of the pharmacy and health care industries to ensure that the entire regulation, not just § 27.506(a), is written in a manner that will encourage pharmacies to participate in the program. We suggest that the Board use this process to ensure that the Program is implemented in such a way that pharmacies are willing to participate, and more importantly, cancer patients have access to unused cancer drugs.

The second concern relates to § 27.506(b) and the income limits for eligibility in the Program. Pursuant to Sections 5.2(b)(3)(ii) and (iv) of the Regulatory Review Act, 71 P.S. §745.5b(b)(3)(ii) and (iv), we question how this section will be implemented and believe it lacks clarity. Under Subsection (b)(2) of the rulemaking, 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 income limits are in Appendix A of the rulemaking and changes to the limits will be posted to the Board's website. We believe

that this approach to amending the income limits could be confusing to the regulated community. If Appendix A is retained in the final-form rulemaking, we suggest that any changes to income limits be made via publication of a notice in the *Pennsylvania Bulletin* on an annual basis and whenever changes are made and also posted on the Board's website. In the alternative, the Board could delete Appendix A and rely on the formula contained in §27.506(b)(2).

We are also concerned that Appendix A includes a reference to current income levels instead of prior year income levels. We believe basing income levels on a patient's prior year income will be easier to implement than basing it on current year income levels. We question how a person's current year income can be accurately calculated before the end of that year.

We have determined this regulation is not reasonable and it is not consistent with the intention of the General Assembly. It also lacks clarity. Additionally, after considering all of the other criteria of the Regulatory Review Act discussed above, we find promulgation of this regulation is not in the public interest.

BY ORDER OF THE COMMISSION:

The regulation # 16A-5423 (IRRC # 2889) from the _____

State Board of Pharmacy

was disapproved on May 16, 2013.



A handwritten signature in cursive script, reading "Silvan B. Lutkewitte, III".

Silvan B. Lutkewitte, III, Chairman