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House of Representatives
Commonwealth of Pennsylvania
Harrisburg

COMMITTEES

PROFESSIONAL LICENSURE,
MAJORITY CHAIR

CONSUMER AFFAIRS

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April 27, 2011

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Kim Kaufman, Executive Director
Independent Regulatory Review Commission
14th Floor, Harristown 2
333 Market Street
Harrisburg, PA

Dear Mr. Kaufman,

Today the House Professional Licensure Committee voted to take no formal action on Proposed Regulation 16A-5423 of the State Board of Pharmacy pertaining to the Cancer Drug Repository Program until final regulation is promulgated and to submit the following comments:

1. The Committee brings to the Board's attention that proposed Regulation 16A-5423 was published in the March 12, 2011 issue of the *Pennsylvania Bulletin,* approximately 2 years and 7 months past the 90 days from the effective date of the Act of May 13, 2008, (P.L.139, No.14).

2. The Committee brings to the Board's attention certain language inconsistencies throughout the proposed regulation and recommends language consistencies as follows:

a. The Committee recognizes it is appropriate for the word "Pennsylvania" to be used before "resident" in §27.506(b)1), even though it is not used within the Act. It is recommended the word "Pennsylvania" also be inserted before "residents" in §27.501.

b. (i). It is recommended the definition *"Original sealed and tamper-evident unit dose packaging"* under §27.502 of the proposed regulation be changed to read: "*Original unopened sealed and tamper-evident unit dose packaging* – Single unit dose packaging of medications from a manufacturer or a repackager registered with the Federal Food and Drug Administration, or from a Pennsylvania licensed pharmacy that included orals, injectables, topicals, and aerosols."

(ii). To align with statutory language "unopened" is inserted before "sealed"; the word "licensed" is replaced with "registered" as the Food and Drug Administration registers repackagers rather than licenses them; and the word "oral" is moved from before "medications" and pluralized ("orals") for clarification purposes.

c. It is recommended the word "of" in §27.503 (b)(5) be replaced with "by"

d. It is recommended the word "Cancer" be inserted before the word "drugs" in §27.503(c)(2) to conform to the term "cancer drug" which is defined in the Act.

e. The Committee recommends the removal of "(1)" in §27.503(e) which relates to the Board's authority to refuse, revoke, or suspend approval of a pharmacy's participation in the program because there is no clause (2).

f. It is recommended the term "medical facility" used throughout the proposed regulation and proposed forms be replaced with the term "health care facility" as defined in the Act.

g. It is recommended in §27.504(a)(2) that the word "original" be inserted before "packaging" and "sealed" inserted after "unopened" to conform with the Act

h. It is recommended in §27.505(e)(3) that the word "unopened" be inserted before the word "sealed."

i. It is recommended in §27.505(e)(4) that the words "sealed and tamper-evident" be inserted before "packaging."

3. The Committee requests an explanation of how topicals and aerosols can be single usage dosages as described in the definition referenced in 2.b. above. The committee recommends the removal of these terms if they cannot be dispensed as single usage dosages.

4. The Committee recommends removing "An individual who is 18 years old or older" in §27.503(d)(1) as the Act does not provide for donation of cancer drugs by individuals. It is also recommended that the wording of this subsection be consistent with the definition of "closed drug delivery system" under the Act. Accordingly, "person or entity making the donation or that person's or" should be removed from §27.503(d)(2)(i).

5. The Committee notes throughout the proposed rulemaking and proposed forms the terms "medical supplies", "supply", and "supplies" are used however the Act deals solely with cancer drugs. It is recommended these terms be completely removed as the board lacks statutory authority to include them.

6. The Committee requests an explanation as to how the Board will make certain repackaging fees are reasonable.

7. The Committee recommends the proposed forms be edited consistent with these recommendations.

Sincerely,

Julie Harhart, Majority Chair
House Professional Licensure Committee

JH/mmgw