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PENNSYLVANIA PHARMACISTS ASSOCIATION

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April 8, 2011

David M. Green, Counsel
State Board of Pharmacy
P.O. Box 2649
Harrisburg, PA 17105

RE: Regulation 16A-5423 – Cancer Drug Repository Program

Dear Mr. Green:

The Pennsylvania Pharmacists Association offers the following comments in response to publication of this proposed regulation as part of the review process. We appreciate the opportunity to file these comments.

We remain concerned with the overall concept behind the law and regulation for this purpose, which involves the re-use and re-dispensing of medications. Anytime the provision of drugs is moved beyond the secure drug distribution and supply chain established in this country to ensure public safety, we are troubled by the implications and risks to patient care. Current state regulations prohibit a pharmacist from restocking items except under very strict circumstances and especially in the circumstance when it has left the premises of the pharmacy (27.102 of the Pharmacy Code).

We are also concerned about the "no cost" provision stated in the regulatory package. Indeed, the pharmacies participating in this program would have considerable costs, of manpower, storage, and compliance with the paperwork. While there is a modest dispensing fee associated with the program, the onerous administrative pieces will clearly have a financial impact. This is one reason why we believe few pharmacies will be able to or interested in participating in this program.

There is also a liability concern for any participating pharmacy. While we believe the act provided some exemption from liability, we also know that there is plenty of opportunity for loopholes and allegations even when such an exemption is provided. Certainly the need to carry any additional professional liability insurance is another cost. This is another reason or concern for pharmacies to decide not to participate.

In addition, we have these much more specific comments:

Section 27.503 (d) (1) references "Donations of cancer drugs and supplies" and in several places in the following parts of this section; yet in the definition section, there is no definition of supplies. Without a clear definition of supplies and their corresponding eligibility for re-use, there will be confusion as to what supplies are considered acceptable for redistribution. c Under **27.502 Definitions,** where tamper-evident packaging is referenced, please note the following. The terminology "tamper-evident" is more closely linked with over the counter drugs (i.e., not prescription drugs which are the focus of this regulation) as defined in 21 CFR 211.132. I do not know of anywhere where the FDA has defined the term "tamper evident" for prescription medications. It may be advisable to use a more generic description that would convey the meaning of tamper-evident without using that exact term which conveys very specific requirements. (e.g. specific labeling that identifies the tamper resistant features, etc). Obviously, there are references to "tamper-evident" throughout the document that require similar review.

Also in **27.502 Definitions**, it may be a good idea to separate out the description of injectables, topicals and aerosols in the definition section. This would make it easier to include them in the eligible drugs section 27.504 (a) (3), especially since they don't quite fit the definitions of eligible drugs currently listed in 27.504 (a) (1)and 27.504 (a) (2).

In **Section 27.503 (d) (2) (ii),** it 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. Presumably, in many cases these drugs are going to be donated by average citizens. Having them attest that the drugs are not adulterated and misbranded may be problematic if they do not know the definitions of adulteration and misbranding. Additionally, it is likely that they will simply wish to donate the drugs and will simply state this regardless. Perhaps the attestation language could be revised to reflect more easily understood language that would convey the same meaning. However, I think it is important to realize that this really is not much of a safeguard.

Section 27.504 – Please see the comment above regarding the inclusion of the description of injectables, topicals, and aerosols separately as eligible drugs in 27.504(a) (3).

Section 27.505 (b) – requires the inspection of all drugs prior to dispensing to determine if they are adulterated or misbranded. Although a pharmacist can check for obvious signs of adulteration or misbranding, in the context of this regulation, we believe that the goal here is to check for "obvious" signs of adulteration or misbranding (i.e., the pharmacist is not going to be able to be conclusive as to whether a drug is adulterated or misbranded, and is simply making his/her best effort in this regard.) It would be impossible to identify based upon a visual inspection alone, all potential for misbranding or adulterations and somehow this needs to be clearly pointed out in both the regulation and to any patient for whom the drug is dispensed.

27.505 (c) Disposition In this section, it would be a good idea to include language that reflects compliance with all federal and state laws, especially now where so much national attention is being devoted to figuring out how to dispose of unused medications properly. It is inevitable that there will be forthcoming legislation on how to dispose of medications properly and Pennsylvania already has some specific requirements for collection.

27.505 (e) (4) That a visual inspection has been conducted by the pharmacist to ensure that the drug has not expired, has not been adulterated or misbranded....
In this section, the word "ensure" is too strong as it connotes an absolute assurance that the drug is not expired, adulterated, or misbranded. This relates to the comments above that for **27.505 (b).**

27.505 (f) (3) Currently, (f)(3) (vii) adds the term "if applicable". We are not sure why this is "if applicable." Or maybe it should also be added to (v) (viii) (ix) and (x) as well.

27.506 (a) (1) According to this section, the patient must have cancer for enrollment in the program. Does the pharmacist require documentation of the cancer diagnosis, and if so what is considered appropriate documentation (patient statement, physician written order, physician verbal statement, etc.).

27.506(a) (2) The patient does not possess or has limited prescription drug coverage related to the treatment of the patient's cancer such that the coverage limits prevent the patient from obtaining cancer drugs. This criteria for eligibility seems unnecessary. It is arbitrary and not verifiable whether or not the coverage limits of a patient's insurance are adequate. It appears sufficient to simply include the other eligibility requirements (i.e., that the patient has cancer; the patient is not eligible for Medicaid prescription coverage, and does not exceed the 350% Poverty guidelines. We would be concerned of the ability to verify that this requirement is even met.

27.506(a) (3) How would this actually be accomplished? The assumption here is that the financial eligibility check would be performed by the Department of Public Welfare through Medicaid offices and that some type of proof of eligibility would be provided to the patient? This should be more clearly stated.

On the form, Application for Prescription Drug Repository, page 3, section IV certification. The first item to be "certified" deals with items and standards that ALL pharmacies must already meet as a condition for licensure' therefore is redundant and unnecessary and almost insulting to an already licensed pharmacy to further certify.

Somewhere in the discussion of eligible drugs, it should be mentioned that prescription "samples" may be accepted for the cancer repository, assuming that they meet all other requirements. It is conceivable that an indigent patient may have previously received samples from a physician, is now deceased, and the spouse is looking to donate them to the program. Under the current State Board regulations, samples are not allowed in a retail pharmacy. However, these would seem like a more natural and potentially safe venue for this program.

Finally, there has to be a discussion of continuity of care. We imagine that it could be very difficult for a patient to be able to obtain specific drugs through this program, given the concerns and more likely limited uptake of the program. It is also probably unlikely that they could obtain the same drugs on any kind of regular basis, so we are not sure this really solves the dilemma of adequate care for patients in this situation.

Again, thank you for the opportunity to provide comments to this regulation. If you have any additional questions, please feel free to contact me.

Sincerely,

Patricia A. Epple, CAE
CEO