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Pennsylvania Academy of Ophthalmology

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The Eye Physicians and Surgeons

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April 4, 2017

Kerry Maloney, Board Counsel
State Board of Pharmacy
RA-STRegulatoryCounsel@pa.gov

Re: State Board of Pharmacy
Proposed Regulations: Compounding
IRRC #3163

Dear Mr. Maloney,:

I am writing as President of the Pennsylvania Academy of Ophthalmology (PAO) in regards to Regulation #16A-5419: Compounding. The PAO supports the State Board of Pharmacy's efforts to strengthen regulations specific to compounding pharmacies. We believe that these regulations are necessary to ensure the safety of Pennsylvanians; however, we also wish to ensure that patients continue to have access to compounded medicines on a timely and possibly emergent basis.

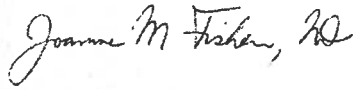
The PAO respectfully submits the following questions and comments regarding Regulation #16A-5419: Compounding.

1. Section 27.604 requires a prescription for a specific patient; however, section 27.605 permits wholesale distribution to a medical practitioner to administer to individual patients. Section 604 uses the term "specific patient." Section 605, in contrast, uses the term "individual patient." Does the term "individual patient" mean that specific patients don't have to be identified for each compounded drug that is delivered via wholesale distribution to a medical practitioner? The nature of our medical practice and the needs of our patients often require ophthalmologists to have certain sterile and non-sterile medications on site to prevent potentially disastrous situations, such as permanent blindness. If section 27.605 allows ophthalmologists to bulk purchase these and identify each patient and the specific lot number received at the time the medication is prescribed and administered, the PAO has no objections.
2. Question 15 of the Regulatory Analysis Form states that all pharmacies and pharmacists who compound drugs would be required to comply with the provisions of this rulemaking. Would the proposed regulations prohibit physicians from compounding within their offices? Ophthalmologists, specifically retinal and corneal specialists mix concentrated antibiotics for topical and intravitreal use just before administration. This is a safe and necessary practice. If this is not allowed under the proposed rule, we **strongly** urge adding an exception for this in emergent or urgent situations when delay could cause irreversible harm including blindness and loss of the eye. Examples of this include bacterial corneal ulcers with impending corneal perforation and acute endophthalmitis.
3. While "beyond use dates" are not included in the proposed regulations, we would note that this issue is currently being addressed by the FDA and national medical societies. We anticipate that the State Board of Pharmacy would follow the final determination at the federal level.

Mr. Kerry Maloney
April 4, 2017
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Thank you for allowing us to comment on the proposed regulations. If you have any questions about the above comments, please contact PAO Executive Director Jennifer Keeler at jkeeler@pamedsoc.org.

Sincerely,

A handwritten signature in cursive script that reads "Joanna M. Fisher, MD".

Joanna M. Fisher, MD
President

cc: Independent Regulatory Review Commission
via email, irrc@irrc.state.pa.us