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PENNSYLVANIA
Academy of Dermatology and Dermatologic Surgery

April 5, 2017

Independent Regulatory Review Commission
333 Market St, 14th Floor
Harrisburg, PA 17101

Re: Regulation #16A-5419: Compounding

Dear Members of the Independent Regulatory Review Commission,

On behalf of the undersigned organizations, representing approximately 400 dermatologists in Pennsylvania and 13,500 dermatologists nationwide, we appreciate the opportunity to provide comments on recently proposed rules governing compounding.

As dermatologists who diagnose and treat more than 3,000 skin diseases, including skin cancer, eczema, infections, psoriasis, immunologic diseases, and many genetic disorders, we rely heavily on compounded pharmaceutical products. Prescribing and/or directly administering compounded products allows us to tailor treatments to the unique needs of our patients in a timely manner, resulting in better outcomes. The compounding in which dermatologists engage involves low-risk practices such as compounding or administering compounded topical medication and diluting solutions for intralesional injections, which has been done safely for decades. The compounds used in the practice of dermatology do not involve the risks associated with intravenous, intrathecal, or intramuscular injections.

Our organizations share the goal of providing safe, effective and high quality patient care. We have held many discussions with other medical and pharmaceutical societies, as well as accreditation agencies, and agree that we must work together to prevent the type of compounding tragedies like those that occurred at the New England Compounding Center. In order to ensure patients will continue to have access to compounded medications, we respectfully request clarification from and provide recommendations to the Independent Regulatory Review Commission and Pennsylvania State Board of Pharmacy on the following:

Section 27.601: This section would require sterile and non-sterile compounding to be done in accordance with USP chapters. Although the description section of the proposal states that this section applies to pharmacists, it is unclear from the language itself if this proposal would apply

to pharmacies or physician offices. The US Pharmacopeial Convention (USP), the leading scientific body responsible for establishing standards for the safe manufacturing, distribution and consumption of drugs in the US and worldwide, is currently reviewing and potentially revising Chapter 797 governing Pharmaceutical Compounding—Sterile Preparations. After receiving more than 8,000 comments, some of which opposed the burdensome requirements on physicians, USP is expected to release a new draft for stakeholder input. Moving forward with the proposal before USP finalizes Chapter 797 is premature and has the potential to create inconsistency and confusion in the regulation of compounding drugs.

Section 27.602: This section incorporates the Food and Drug Administration's (FDA) draft guidance on compounding drugs that are essentially copies of commercially available drug products. While we support retaining proposed language allowing copies if in the "best interest of the patient", this could create a conflict between federal and state law. Should the FDA restrict compounding essentially copies by adopting its guidance document as law, would the FDA's federal guidance supersede Pennsylvania law?

Section 27.603: This section is consistent with the FDA guidance documents concerning bulk drug substances; however, it provides an exception for bulk drug substances that are not subject to a monograph. Such substances could meet "peer reviewed medical literature and, in professional judgment of pharmacist & prescriber, demonstrates effectiveness of bulk drug substance. Would the bulk drug substances be available for this reason despite the federal law and FDA guidance documents?

Section 27.608: The first sentence of this section appears to limit protective apparel requirements to pharmacy personnel, but clarification is needed. Does this solely apply to pharmacy personnel or does it extend to physician offices? We also reiterate our concerns above concerning the adoption of USP standards. We support the Board's efforts to ensure the safety of sterile compounded products; however, it is not reasonable to expect dermatologists who prepare simple compounds or dilutions used for intradermal or subcutaneous injections to adhere to the same standards as large compounding facilities. The proposal would limit the ability of physician offices to prepare and use compounds used for intradermal or subcutaneous injections, as they have safely done for decades.

Section 27.610 through 27.615: Do these sections apply exclusively to pharmacies? If it applies to physician offices, we oppose the applicability of UPS 797 to physician offices for the reasons set forth above.

Section 27.623: This section sets forth the production record requirements for bulk compounding. We seek clarification concerning whether this applies to physicians who use bulk substances.

We appreciate the opportunity to provide these comments. The Academy and PAD aim to preserve the common practice of dermatologists treating their own patients using products compounded in their individual practice settings. The compounding in which dermatologists engage frequently involves very low risk practices such as compounding or administering compounded diluted solutions for intralesional injections. We urge the IRCC and Board to

consider the risks associated with the different methods of administration as it reviews the proposed compounding rules. Additionally, we would be pleased to facilitate understanding of concerns from dermatologists who practice in an office-based setting. Should you have any questions, please do not hesitate to contact Lisa Albany, associate director, state policy for the American Academy of Dermatology Association at 202-842-3555 or lalbany@aad.org.

Sincerely,

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