Alliance for Pharmacy Compounding

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July 16th, 2024

New Mexico Board of Pharmacy
5500 San Antonio Dr. NE, Suite C
Albuquerque, NM 87109

Subject: Comment on Proposed Rulemaking - Amendments to 16.19.6 NMAC

Dear Members of the New Mexico Board of Pharmacy,

We are writing to provide comments on the proposed amendments to 16.19.6 NMAC, as published in the New Mexico Register, Volume XXXV, Issue 11. The Alliance for Pharmacy Compounding (APC) supports the alignment of New Mexico's regulations with the United States Pharmacopeia (USP) chapters on compounding. This alignment is crucial for ensuring consistent, high-quality compounding practices that protect patient safety.

However, we would like to address a specific concern regarding the use of flavoring agents in compounded medications. The proposed rules suggest that pharmacists must ensure that any flavoring agents used are inert for all drug products. While we understand the intent behind this requirement, it is important to recognize the practical limitations that pharmacists face in this regard.

Flavoring agents are commonly used in compounding to improve the palatability of medications, thereby enhancing patient compliance. However, the determination of whether a flavoring agent is inert for any and all drug products is a complex and often impossible task. The chemical interactions between flavoring agents and drug product or specific active pharmaceutical ingredients (APIs) can vary significantly depending on the specific drug formulation. This complexity is further compounded by the lack of comprehensive data on the interactions between many flavoring agents and various drug product and/or APIs.

To require pharmacists to ensure that flavoring agents are inert in all potential drug products places an unrealistic burden on pharmacists. Instead, we propose that the regulations emphasize consulting this document from USP, https://go.usp.org/795_Flavoring.pdf, which is a resource for adding flavorings to conventionally manufactured products. This approach balances the need for patient safety with the practical realities of pharmacy practice.

Moreover, we appreciate the Board's efforts to align with USP chapters <795> and <797>, which provide clear guidelines on non-sterile and sterile compounding practices, respectively. These guidelines are based on scientific evidence and expert consensus, ensuring that compounded medications meet high standards of quality and safety.

In conclusion, while we support the proposed amendments and the alignment with USP standards, we urge the Board to reconsider the requirement for pharmacists to guarantee that flavoring agents are inert in all drug products.

Thank you for considering our comments. We look forward to continued collaboration with the New Mexico Board of Pharmacy to advance the practice of pharmacy compounding and safeguard public health.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
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