



February 10, 2023

The Honorable Maria Serpa, Chair  
Enforcement and Compounding Committee  
California State Board of Pharmacy  
2720 Gateway Oaks Drive, Suite 100  
Sacramento, CA 95833

**Re: Proposed Changes to Regulations Related to Pharmaceutical Compounding of Nonsterile Preparations: Flavoring**

Dear Vice President Serpa,

On behalf of the California Retailers Association (CRA), I write to urge the Board of Pharmacy to ensure that pharmacies in California can continue to add flavor to liquid and suspension medications by continuing to exclude the addition of flavoring agents from the definition of compounding.

We believe that the addition of flavoring to commercially prepared medications does not constitute compounding, as it does not alter the route of administration, dosage form or efficacy of a medication. Therefore, the addition of flavoring should not be considered compounding and the requirements of USP 795 should not apply to the addition of flavoring to prescription drugs. However, we understand that revised guidance related to USP General Chapter 795 has been published to specify that flavoring constitutes compounding. Given that this is guidance, and is not specified in USP Chapter 795, we urge the Board of Pharmacy to maintain the definition of compounding in current regulation as follows:

**Article 4.5 Compounding 1735. Compounding in Licensed Pharmacies (b) “Compounding” does not include reconstitution of a drug pursuant to a manufacturer’s direction(s), nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability**

Since this definition was enacted in 2014, there have been no reported incidents of harm to any patients. Flavoring is typically used in children’s medications, including common antibiotics like Amoxicillin. Prescribers do not typically consider the taste of medications when prescribing them, so pharmacists most commonly add flavoring to liquids and suspensions with the intent of customizing tastes to increase patient adherence – not to alter the medication nor medical effectiveness of the medication. Millions of children’s medications have been flavored in California since 2014 with no adverse effects. Flavoring is highly beneficial to patients and makes it much easier for children to take their required medication.

If flavoring is no longer excluded from the definition of compounding, most pharmacies in California will stop offering flavoring, which could result in children refusing their medications or parents inventing their own, possibly dangerous approaches to persuade their children to take their medicine.

For these reasons, we respectfully request that the Board continue to exclude flavoring from the definition of compounding. If this is not possible, we encourage the Board to examine alternative ways to ensure pharmacies are able to continue to offer flavoring. The flavoring additives that are added to prescriptions are not prescription drugs, have been deemed safe and therefore do not require a physician's approval or oversight for utilization and therefore should not be considered nonsterile compounding.

Thank you for considering our comments on this important issue. Please do not hesitate to contact Lindsay Gullahorn or Jennifer Snyder with Capitol Advocacy at [lgullahorn@capitoladvocacy.com](mailto:lgullahorn@capitoladvocacy.com) or [jsnyder@capitoladvocacy.com](mailto:jsnyder@capitoladvocacy.com) if you have any questions.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Rachel Michelin', is positioned above the typed name.

Rachel Michelin  
President & CEO  
California Retailers Association

cc: Seung Oh, President, Board of Pharmacy  
Anne Sodergren, Executive Officer, Board of Pharmacy  
Kimberly Kirchmeyer, Director, Department of Consumer Affairs  
Richard Figueroa, Deputy Cabinet Secretary, Office of Governor Newsom