Date of Hearing: September 13, 2023

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Marc Berman, Chair
AB 782 (McKinnor) – As Amended August 21, 2023

NOTE: This bill is being heard pursuant to Assembly Rule 77.2 for concurrence in Senate amendments only.

SUBJECT: Pharmacies: compounding.

SUMMARY: Exempts the addition of flavoring agents to a drug from the state's requirement that such actions comply with pharmacy compounding standards under the United States Pharmacopeia-National Formulary (USP).

EXISTING LAW:

1) Establishes the Pharmacy Law. (Business and Professions Code (BPC) §§ 4000 *et seq.*)

2) Establishes the California State Board of Pharmacy (BOP) to administer and enforce the Pharmacy Law, comprised of seven pharmacists and six public members. (BPC § 4002)

3) Provides that protection of the public shall be the highest priority for the BOP in exercising its licensing, regulatory, and disciplinary functions. (BPC § 4001.1)

4) Authorizes the BOP to adopt rules and regulations as may be necessary for the protection of the public. (BPC § 4005)

5) Defines "pharmacy" as an area, place, or premises licensed by the BOP in which the profession of pharmacy is practiced and where prescriptions are compounded. (BPC § 4037)

6) Defines "pharmacist" as a natural person to whom a license has been issued by the BOP which is required for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription. (BPC § 4036; BPC § 4051)

7) Requires persons seeking to conduct a pharmacy in California to obtain a license from the BOP and requires applications for renewal of a pharmacy license to include notification to the BOP regarding compounding practices, including compounded human drug preparations distributed outside of the state. (BPC § 4110)

8) Requires each pharmacy to designate a pharmacist-in-charge, subject to approval by the BOP, who is responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. (BPC § 4113)

9) Requires pharmacies that contract to compound a drug for parenteral therapy to report that contractual arrangement to the BOP within 30 days of commencing the compounding. (BPC § 4123)

10) Requires every pharmacy to establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. (BPC § 4125)

11) Provides that the compounding of drug preparations by a pharmacy for furnishing, distribution, or use in California shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary (USP), including relevant testing and quality assurance; authorizes the BOP to adopt regulations to impose additional standards for compounding drug preparations. (BPC § 4126.8)

12) Requires a pharmacy that issues a recall notice regarding a nonsterile compounded drug product to contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice under specified circumstances. (BPC § 4126.9)

13) Authorizes a pharmacy to distribute compounded human drug preparations interstate if specified conditions are met. (BPC § 4126.10)

14) Requires clinics to retain a consulting pharmacist to approve policies and procedures and to certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of the Pharmacy Law. (BPC § 4192)

15) Provides that the BOP shall take action against any licensee who is guilty of unprofessional conduct, with various specific examples provided. (BPC § 4301)

16) Subjects a licensed pharmacist to formal discipline for unprofessional conduct that includes acts or omissions that involve the following:

    a) Inappropriate exercise of their education, training, or experience as a pharmacist.

    b) The failure to exercise or implement their best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or the provision of services.

    c) The failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

    d) The failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

    (BPC § 4306.5)

THIS BILL:

1) Exempts reconstitution of a drug pursuant to a manufacturer's directions, the sole act of tablet splitting or crushing, capsule opening, or the addition of a flavoring agent to enhance palatability from the definition of "compounding."

2) Requires a pharmacy to retain documentation that a flavoring agent was added to a prescription and to make that documentation available to the BOP, or an agent of the board, upon request.

FISCAL EFFECT: Pursuant to Senate Rule 28.8, negligible state costs.

COMMENTS:

Purpose. This bill is sponsored by the author. According to the author:

> "Flavoring for children's medications has been available in pharmacies across California for decades. At least 3,000 pharmacies in California currently provide this service. It's one of the most effective tools available to reduce the stress around medicine-time and increase medication adherence. It is estimated that over 6 million medications have been flavored in California and 200 million across the country over the past 25 years, without incident. The California Board of Pharmacy has consistently permitted medication flavoring from at least 2010. However, because of an unintended consequence of AB 973 (Irwin, 2019) the Board of Pharmacy is now poised to reverse their position on the issue and adopt regulations that would require community pharmacies to adopt over 80 new rules and regulations just to continue adding flavor to kid's medicine. The practical effect of this change is that retail pharmacies will cease to offer flavoring, and the practice will be limited to compounding pharmacies that are already complying with these requirements. The problem is that compounding pharmacies are few and far between—even more so in rural or low-income areas. AB 782 resolves this issue by maintaining the status quo in California and ensuring that the over 5,000 community and independent pharmacies throughout the state can continue to add flavoring to children's medications. It does so by placing in statute the California Board of Pharmacy's (Board) current regulation and long-held position exempting flavoring from the definition of 'compounding.'"

Background.

According to the federal Food and Drug Administration (FDA), drug compounding is generally described as the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Combining two or more drugs is a form of compounding, as is the reconstitution of a drug into another ingestible form. Compounded drugs are not approved by the FDA for safety or effectiveness.

Pharmacy professionals who engage in the practice of drug compounding are required to obtain a license from the BOP. However, prior to 2020, there were no state laws that specifically outline requirements for the compounding of prescription drugs. Partially in response to a multistate outbreak of fungal meningitis for which the unsafe compounding of a preservative-free steroid injection resulted in numerous deaths, the BOP sponsored legislation in 2019 to provide that compounding in California must be performed consistent with consistent with standards established in the pharmacy compounding chapters of the current version of the USP.

The United States Pharmacopeia-National Formulary is a combination of two compendia published by two longstanding nonprofits: the USP, published by the United States Pharmacopeial Convention; and the National Formulary, published by the American Pharmaceutical Association. As the FDA's officially designated compendium, the USP sets numerous standards for drug ingredients and manufacturing processes, including testing and quality assurance. Generally speaking, drug products and ingredients sold in the United States must conform to the USP to be considered unadulterated and of minimum quality.

Several years after the enactment of the 2019 legislation, concerns emerged that USP standards for compounding would apply to the addition of flavoring to medication. USP General Chapter 795 sets minimum standards for preparing compounded nonsterile preparations. These standards include minimum personnel qualifications, personal hygiene and garbing requirements, and cleaning and sanitizing protocols.

For purposes of its General Chapter 795, the USP defines nonsterile compounding as "combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation." The USP has published a position statement affirming that it has considered the flavoring of conventionally manufactured medications to be within the scope of General Chapter 795 since 2004. In formal commentary published in November 2022, the USP responded to a comment indicating that the addition of flavoring agents should not be required to meet nonsterile compounding requirements with the following statement:

> "Flavorings are organic chemicals with reactive functional groups including acids, alcohols, aldehydes, amides, amines, esters, ketones, and lactams. Flavorings are not always labeled with their full ingredients and may contain solvents. Minor components in a flavoring system can impact the stability of a CNSP. Impacts on stability can lead to degradation, production of harmful impurities, and/or reduced bioavailability. Flavorings can impact levels of impurities while having no impact on assay values."

The FDA has not officially issued guidance relating to the question of whether adding flavoring constitutes compounding. However, correspondence between the FDA and the BOP confirmed that "the addition of a flavoring by a pharmacy to a drug generally would be considered compounding" but that "if the labeling for an FDA-approved drug includes directions to do so, adding flavoring to the drug in accordance with these directions would not be considered compounding." This would indicate that the addition of flavoring does *not* need to comply with General Chapter 795 if directions for flavoring were included on an FDA-approved drug label.

While the USP and the FDA have considered the most cases of adding flavoring to constitute compounding since years before the enactment of the 2019 legislation, the BOP's regulations previously exempted addition of flavors. Specifically, the BOP's regulations have stated:

> "'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."[1]

Because the BOP's regulations would seemingly be out of compliance with the USP, the BOP has taken steps to reconcile its regulations and remove the above exemptions. This has caused concerns amongst stakeholders that many pharmacies who do not wish to comply with the USP General Chapter 795 standards will cease to engage in the addition of flavoring. As a result, this bill has been introduced to statutorily restore the exemption for flavoring for purposes of California, notwithstanding the provisions of the USP. The bill would codify the language currently contained in regulations and effectively authorize specified noncompliance with the USP in state compounding requirements.

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[1] Cal. Code Regs. Tit. 16, § 1735

The author and supporters believe that this bill will ensure that children and other vulnerable patients are able to take needed medication that would not otherwise be palatable. This is due to a perception that many pharmacies would be reluctant to engage in flavoring if they were required to comply with stricter compounding requirements. The author contends that this exemption will not pose any increased risk to patients but would merely preserve a status quo that existed prior to 2019.

Prior Related Legislation.

AB 973 (Irwin, Chapter 184, Statutes of 2020) established the requirement that the compounding of drug preparations by a pharmacy be consistent with standards established in the pharmacy compounding chapters of the current version of the USP.

ARGUMENTS IN SUPPORT:

FlavorX, a company that sells medication flavoring products, supports this bill, writing: "Without legislative action to exempt flavoring of children's medications, parents will be left to again deal with the difficulties of getting their toddlers and children to take prescribed medications. Even if parents are willing to travel long distances to find a compounding pharmacy, they will likely have to pay an increased cost of flavoring to cover the costs of pharmacies that decide to make this conversion."

ARGUMENTS IN OPPOSITION:

The **California State Board of Pharmacy** (BOP) opposes this bill unless amended, writing: "The Board supports the long-standing pharmacy practice of compounding, including the use of flavoring agents, consistent with legal requirements. The Board believes the approach taken in Assembly Bill 782 places consumers at risk and runs afoul of national standards and state and federal law. The Board believes a more appropriate approach to ensure access to flavorings remains is to focus on how to operationalize the USP <795> requirements to assist pharmacists and pharmacies that choose to provide this service to patients."

POLICY ISSUE(S) FOR CONSIDERATION:

Inconsistency with Federal Standards. The intent of the 2019 legislation was to set baseline standards in California for nonsterile compounding that align with what federal agencies require under the USP. However, this bill would create a deliberate misalignment between state and federal standards by exempting flavoring from the state's definition of compounding despite its inclusion in the USP's definition. Because the BOP regularly enforces both state as well as federal laws as part of its public protection mission, this misalignment would arguably cause confusion amongst pharmacy professionals and frustrate the BOP's efforts to enforce clearly delineated requirements.

However, these potential concerns, as articulated by the BOP, should be balanced against the author's concern for retaining current access to flavored medications. It should also be considered that there is an arguable lack of evidence that prior law resulted in any identifiable consumer harm. Nevertheless, the author should deliberatively consider the BOP's concerns and discussions about how to safely and effectively preserve access to medication flavoring should persist beyond this session year regardless of whether this measure is chaptered into law.

REGISTERED SUPPORT:

Association of Regional Center Agencies
California Coalition for Children's Safety and Health
California Retailers Association
California Society of Health System Pharmacists
Children's Specialty Care Coalition
FlavorX
Jordan's Guardian Angels
National Association of Chain Drug Stores

REGISTERED OPPOSITION:

California State Board of Pharmacy

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