NORWOOD ASSOCIATES
Government Relations

TO: Members, California Board of Pharmacy
Legislation/Regulation Committee

FROM: Norwood Associates, LLC on behalf of FLAVORx

DATE: July 13, 2023

RE: AB 782 (McKinnor): Pharmacies: Compounding—**SUPPORT**

On behalf of our client, **FLAVORx**, we are writing to request the Board of Pharmacy's Legislation/Regulation Committee support AB 782 (McKinnor), as amended June 27, 2023.

AB 782 simply maintains the status quo in California with regard to flavoring children's medications by placing in statute the California Board of Pharmacy's (Board) current regulation and long-held position exempting flavoring from the definition of "compounding."

The Board of Pharmacy has consistently treated medication flavoring as a pharmacy practice outside of the realm of compounding, despite the publication of USP Chapter 795 in 2004 and its subsequent revision in 2014. Per USP's recent guidance, the USP definition of compounding has always included flavoring. Do not be misled into thinking USP's position on flavoring is new. It is not. They say so themselves.

In 2010 the Board took an explicit position on flavoring through 16 CCR § 1735, which was subsequently updated in 2017.

> "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."

The only intervening event affecting this policy was the enactment of AB 973 (Irwin, Chapter 184, Statutes of 2019). AB 973 required the compounding of drug preparations by a pharmacy to be consistent with standards established in the current version of the USP NF, including relevant testing and quality assurance. As you may be aware, that legislation had nothing whatsoever to do with the flavoring of children's medications. No safety issues have arisen related to flavoring. No child has been harmed as a result of flavoring. In fact, the author of AB 973 is a co-author of AB 782, citing the current situation as an unintended consequence.

The Board is now poised to adopt the 2022 USP standards and has taken the position that maintaining their current exemption for flavoring (Section 1735 above) from compounding would be in conflict with AB 973, thus tying the Board's hands to force a change in policy. AB 782 simply resolves this conflict by amending the mandate of AB 973 to specifically exempt flavoring.

Status quo being maintained, there is zero financial impact to California as a result of AB 782's passage. In fact, should AB 782 not pass, there is a massive potential cost to the state. Education of pharmacists on the new requirements, to enforcement activities to ensure compliance are the most obvious. If

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pharmacies choose to comply with the onerous USP requirements the board has proposed (see attached for the complete list of USP 795 requirements), pharmacists will be asked to do more for a service they currently provide without issue. There is simply no good reason to put more on the pharmacist's plate when they are already stressed to the max.

Additionally, pharmacies will also surely pass on the additional costs of compliance to their customers, making an "Oppose" vote on AB 782 a de facto tax on California's parents. Since we know most pharmacies will choose not to offer flavoring if it is regulated as compounding, the hidden but very real cost comes from children not taking their medicine as they should thus staying sick longer, being contagious longer, having to go back to the doctor's office, and parents staying home from work longer. AB 782 is a good bill because it ensures children will be able to take the medicine they so desperately need. It's a better bill because it will save the state and its taxpayers money.

We now have come to understand that the Board is also concerned that the passage of AB 782 could potentially put California's pharmacies in the position of violating federal law. That has not been the case with regard to the Board's current regulation since 2010 or even after the enactment of AB 973, and it would not be the case going forward. Additionally, this has not been the case in any pharmacy anywhere in the country, where flavoring is predominantly treated, just as it is in California, as a basic pharmacy practice outside the scope of compounding. This argument is misplaced.

California currently exempts medication flavoring from its definition of "compounding." Thus, the resulting flavored drug preparation would not be considered a "compounded drug" under California's regulations and, as a result, would not be subject to USP Chapter 795 as the resulting drug product is not a nonsterile compounded preparation. Likewise, should the California Legislature enact AB 782, which expressly exempts medication flavoring from California's definition of compounding, that too would take flavoring outside of the compounding requirements in USP Chapter 795.

We have taken the liberty of including a more detailed legal opinion relative to this issue, attached.

For all of the above-stated reasons, we urge the Legislation/Regulation Committee to vote to SUPPORT AB 782.

Please do not hesitate to contact our office should you have any questions or would like additional information. Thank you in advance for your consideration of this request.

Attachments

USP 795 Requirements – The Musts

Pharmacy must have a Designated Person (DP) who is responsible and accountable for the performance and operation of the facility and personnel.

All personnel must be trained and demonstrate proficiency in the following core competencies:

- Handy hygiene
- Garbing
- Cleaning & Sanitizing
- Component selection, handling, and transport
- Performing calculations
- Measuring and mixing
- Proper use of equipment and devices selected to compound CNSPs
- Documentation of the compounding process (Master Formulation Records and Compounding Records)

All personnel must undergo annual refresher training to demonstrate competency.

The DP is responsible for implementing the training program and evaluating competency.

Training must be documented and retained.

All personnel must:

- Remove personal outer garments
- Remove all hand, wrist, and other exposed jewelry or piercing that can interfere with the effectiveness of the garb or hand hygiene
- Remove headphones and earphones

Hands must be washed for at least 30 seconds and dried thoroughly before donning gloves.

Gloves must be worn for each CNSP and inspected for punctures tears or holes and replaced if necessary.

A designated compounding area is required.

A source of hot and cold water and an easily accessible sink must be available.

All components, equipment, and containers must be stored off the floor.

Storage area temperature must be monitored daily, and results must be logged and retrievable.

All surfaces must be cleaned and sanitized. This must be documented.

If a closed system measuring device is required, BSCs and CVEs must be certified every 12 months or/and directed by the manufacturer and all applicable laws and regulations.

Active Pharmaceutical Ingredients (APIs) must comply with the USP-NF Monograph if there is one and must be sourced from an FDA registered facility.

Master Formulation record must include at least the following:

- Name, strength or activity, and dosage form of the CNSP
- Identities and amounts of all components; if applicable, relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility)
- Container closure system(s)
- Complete instructions for preparing the CNSP including equipment, supplies, and description of compounding steps
- Physical description of the final CNSP
- Beyond-use date (BUD) and storage requirements
- Reference source to support the assigned BUD
- If applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s)
- Labeling requirements (e.g., shake well)
- Quality control (QC) procedures (e.g., pH testing, visual inspection) and expected results
- Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)

A Compounding Record must be created for all CNSPs.

- Be reviewed for completeness before the CNSP is release
- Name or other unique identifier of person completing the review and date of the review
- Permit traceability of all components in case of a recall or quality issue

A CR must include at least the following:

- Name, strength or activity, and dosage form of the CNSP
- Date—or date and time—of preparation of the CNSP
- Assigned internal identification number (e.g., prescription, order, or lot number)
- A method to identify the individuals involved in the compounding process and individuals verifying the final CNSP
- Name, vendor or manufacturer, lot number, and expiration date of each component
- Weight or measurement of each component
- Total quantity of the CNSP compounded
- Assigned beyond-use date (BUD) and storage requirements
- If applicable, calculations to determine and verify quantities and/or concentrations of components activity of the API(s)
- Physical description of the final CNSP
- Results of quality control procedures (e.g., pH testing and visual inspection)
- MFR reference for the CNSP

Label must contain:

- Assigned internal identification number (e.g., prescription, barcode or lot number)
- Chemical and/or generic name(s), or active ingredient(s), and amounts or concentrations
- Dosage form
- Total amount or volume
- Storage conditions
- BUD, the date, or the hour beyond which the preparation cannot be used and must be discarded.

Labeling on the CNSP should display:

- Route of administration
- Indication that the preparation is compounded
- Any special handling instructions
- Any warning statements that are applicable
- Name and contact information of the compounding facility if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded

Facilities must develop SOPs on all aspects of the compounding operation and all personnel must be trained on the facility's SOPs.

Must have a formal, written QA and QC program and that program must be reviewed at least once every 12 months by the designated person.

Results of review must be documented, and action taken as necessary.

Must have a Recall SOP and procedures in place.

Must have a Complaint SOP and procedures in place, for handling complaints and adverse event reports.

Documentation: Must have and maintain written or electronic documentation to demonstrate compliance with chapter.

Documentation must include, but is not limited to, the following:

- Personnel training, competency assessment, and qualification records including corrective actions for any failures
- Equipment records (e.g., calibration, verification, and maintenance reports)
- Receipt of components
- SOPs, Master Formulation Records, and Compounding Records
- Release testing, including corrective actions for any failures
- Results of investigations and corrective actions
- Records of cleaning and sanitizing the designated area
- Temperature logs
- Accommodations to personnel compounding CNSPs
- Information related to complaints and adverse events including corrective actions taken
- Any required routine review (e.g., yearly review of QA/Q, yearly review of chemical hazard and disposal information)

All required Compounding Records must be readily retrievable for at least 2 years after preparation or as required by applicable regulatory bodies.

USP 795 Requirements – The Shoulds

Gloves should be wiped or replaced before beginning a CNSP with different components.

Garb should be worn as needed to protect personnel or prevent contamination:

- Gown may be reused for one shift if not soiled and if it is retained in the compounding area.
- Gloves, shoe covers, hair covers, facial hair covers, face masks or heard coverings must be replaced with new ones after each use.

Designated compounding area should not be carpeted.

All components other than the APIs should have a COA which verifies it meets the USP-NF monograph and any additional specifications.

All components other than the APIs should be manufactured by an FDA registered facility.

Should use purified water, distilled water or RO water to rinse equipment and utensils.

To whom it may concern:

Below are several Q&As that may be used when discussing medication flavoring with representatives from the California Board of Pharmacy.

Question #1: Does the proposed bill AB 782 conflict with the nonsterile compounding standards established by the United States Pharmacopeia?

Answer: No.

The United States Pharmacopoeia ("USP") is a nonprofit organization that, among other things, establishes standards for nonsterile compounding. USP does not enforce its standards; rather, it is through federal or state statute or regulation that government entities may seek to require and enforce USP's compounding standards.

Since the first publication of USP Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations ("Chapter <795>") in 2004, USP has maintained that medication flavoring constitutes compounding as defined in Chapter <795>.[1] However, simply because USP considers medication flavoring to constitute compounding does not mean the California Board of Pharmacy, the governing body responsible for the practice of pharmacy in the State of California, must adhere to that definition or standard. USP is an agency that proposes standards for, among other things, nonsterile compounding. USP's standards do not carry the force of law, they are merely standards that may or may not be adopted. Instead, the California Board of Pharmacy, by regulation, and California's legislature, by statute, have the authority to dictate when and how medication flavoring may occur in the State of California. To be clear, California state law and regulations control, not the standards established by USP (without a state law or regulation specifically incorporating USP standards into that state's practice of pharmacy requirements).

The California Board of Pharmacy has consistently permitted medication flavoring despite the publication of USP Chapter <795> in 2004 and its subsequent revision in 2014, both of which contained USP's definition of compounding that included flavoring. The California Board of Pharmacy previously ratified its position regarding medication flavoring with the promulgation of 16 CCR § 1735(b), which became effective on January 1, 2017.[2] For the Board of Pharmacy to assert that the proposed bill would change California's definition of "compounding" to conflict

[1] *See* Adding Flavor to Conventionally Manufactured Nonsterile Products – USP, *available at:* https://go.usp.org/795_Flavoring.pdf.

[2] The regulation 16 CCR § 1735(b) states: "'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."

with USP Chapter <795>, when the California Board of Pharmacy's own regulations provide otherwise, is simply without merit.

Question #2: Would the proposed bill AB 782 conflict with the Food & Drug Administration's position regarding compounding?

Answer: No.

The U.S. Food & Drug Administration ("FDA") has issued guidance regarding pharmacy compounding under section 503A of the Federal Food, Drug, and Cosmetic Act ("FD&C Act").[3] The guidance explains that for a compounded drug product to be exempt from sections 501(a)(2)(B) [concerning cGMP], 502(f)(1) [concerning the labeling of drugs with adequate directions for use], and 505 [concerning the approval of drugs under NDAs or ANDAs] of the FD&C Act, it must meet the conditions of Section 503A of the FD&C Act. Specifically, the compounded drug product qualifies for the exemptions if, among other things, "[t]he drug product is compounded in compliance with the United States Pharmacopoeia (USP) chapters on pharmacy compounding…".[4]

The California Board of Pharmacy's assertion that the proposed bill would conflict with FDA's position on medication flavoring is misplaced. The first question that must be considered is – whether the act of flavoring a prescription medication is considered "compounding" under California statute or regulation. As mentioned above, California currently exempts medication flavoring from its definition of "compounding." Thus, the resulting flavored drug preparation would not be considered a "compounded drug" under California's regulations and, as a result, would not be subject to USP Chapter <795> as the resulting drug product is not a nonsterile compounded preparation. Likewise, should the California legislature enact AB 782, which expressly exempts medication flavoring from California's definition of compounding, that too would take flavoring outside of the compounding requirements in USP Chapter <795>.

Additionally, even if the act of medication flavoring was to be deemed compounding by the California Board of Pharmacy (notwithstanding its current regulation or proposed bill that would provide otherwise), the FDA guidance document is just that – a guidance document. It does not carry any force of law; rather, it contains nonbinding recommendations from FDA. In fact, the guidance document states just that – "FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited."[5] Therefore, in jurisdictions, such as the State of California, where medication flavoring has been expressly exempted from compounding pursuant to current regulation (and a proposed law), there is no question that flavoring is not compounding, and thus is not subject to USP's compounding standards in Chapter <795>. State law and regulation, which has the force of law, trumps nonbinding guidance from FDA.

[3] Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance, June 2016 Revision 2, available at: https://www.fda.gov/media/94393/download.
[4] *Id*. at pg. 2.
[5] *Id*. at pg. 1.

Question #3: Have other states enacted laws (statutes) exempting medication flavoring from the definition of compounding?

Answer: Yes

The State of Illinois has enacted a law, its Pharmacy Practice Act, that specifically exempts medication flavoring from the State of Illinois' definition of "compounding." The Illinois statute states:

> "Compounding" means the preparation and mixing of components, excluding flavorings, (1) as the result of a prescriber's prescription drug order or initiative based on the prescriber-patient-pharmacist relationship in the course of professional practice or (2) for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing…[6]

Accordingly, there is precedent that the California legislate may choose how to define "compounding," and such a decision, while often delegated to the Board of Pharmacy, is not solely within the purview of the board.

[6] 225 Ill. Comp. Stat. Ann. 85/3(o) (emphasis added).

CHILDREN'S Specialty Care Coalition

Putting California's Children First

Children's Hospital Los Angeles
Medical Group

California Association
of Neonatologists

ChildNet/Specialty Medical Group
Valley Children's Hospital,
Madera

Sutter Children's Center
Sutter Medical Center, Sacramento

Children First Medical Group,
Emeryville

Rady Children's Specialists of
San Diego

Department of Pediatrics
California Pacific Medical Center
San Francisco

UCLA Mattel Children's Hospital
David Geffen School
of Medicine at UCLA

Department of Pediatrics
UC San Diego School of Medicine

Stanford Children's Health
Stanford University School
of Medicine

Department of Pediatrics
UC Davis Children's Hospital

Department of Pediatrics
UCSF Benioff Children's Hospital
UC San Francisco School of Medicine

Department of Pediatrics
UC Irvine Medical Center

Department of Pediatrics
Loma Linda University Faculty
Medical Group, Inc.

Miller Children's and Women's
Hospital Long Beach

CHOC Children's Specialists, Orange
County

Cottage Children's Medical Center -
Santa Barbara

Shriners Hospitals for Children -
Northern California

Community Regional Medical Center,
Fresno

June 29, 2023

The Honorable Richard D. Roth, Chair
Senate Committee on Business, Professions and Economic Development
1021 O Street, Room 3320
Sacramento, CA 95814

RE: AB 782 (McKinnor) – SUPPORT

Dear Chair Roth:

On behalf of the Children's Specialty Care Coalition, I am writing in support of AB 782 (McKinnor) to ensure that pharmacies throughout California can continue to offer flavoring of medications prescribed for toddlers and children.

Pharmacies in California have been flavoring children's liquid medications for decades to help children take their prescribed medicines by enhancing palatability. Flavoring of children's medications is authorized pursuant to Article 4.5, Section 1735 of Board of Pharmacy regulations which states:

> (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.**"

This has been in Board regulations since 2017.

It is estimated that at least six million children have had their medications flavored in California without a single incident of harm coming to a child. Moreover, we estimate that some 180 million medications have been using flavoring systems across the country, again with zero reported incidents of harm. 49 states (including California) currently exempt flavorings from all compounding requirements or merely require documentation of flavor being added to medications, thus allowing pharmacies to provide this basic pharmacy service free of unnecessary regulatory red-tape.

Unfortunately, the California Board of Pharmacy (Board) is poised to reverse its longstanding position by adopting new regulations that would in-effect repeal Section 1735 above. This is an unintended consequence of the passage of AB 973 (Irwin, Chapter 184) in 2019, which directs the Board to require the compounding of drug preparations to be consistent with standards established by the United States Pharmacopeia-National Formulary (USP).

Although AB 973 was specific to compounding, it had nothing to do with flavoring of children's medications. Instead, the argument was that a multistate outbreak of fungal meningitis where unsafe sterile compounding of spinal injections resulted in numerous deaths demonstrated the need for consistent regulatory standards.

The California Board of Pharmacy argues its hands are tied as AB 973 requires the board to adopt the most recent version of USP standards relative to compounding that would have the effect of repealing Section 1735 of the board's current regulations which exclude flavoring from the definition of compounding.

If Section 1735 is repealed it would require thousands of retail pharmacies in California to essentially qualify as a "compounding pharmacy "in order to continue flavorings children's medications. Under current regulations "compounding pharmacies" are the exception, not the rule. For example, there are only three compounding pharmacies in the greater Sacramento area. Compounding pharmacies are even rarer in rural and underserved areas of the state.

Qualifying as a compounding pharmacy is a time consuming and an expensive proposition. It is almost certain that all but a few pharmacies will simply stop flavoring children's medications, rather than incur the time, training, and expense of becoming a compounding pharmacy.

Without urgent legislative action to exempt flavoring of children's medications, California parents will be left to again deal with the difficulties of getting their toddlers and children to take unpalatable 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.

AB 782 simply codifies the Board's existing exemption and position on compounding (found above) so that pharmacies can continue to flavor children's medicine.

CSCC represents over 2,500 pediatric subspecialty care physicians throughout California, and our mission is to ensure that children and youth with complex health care needs have access to equitable, timely and high quality care, provided by pediatric subspecialists who are able to thrive in California's health care environment, through strong leadership, education and advocacy.

If you have any questions, please do not hesitate to contact CSCC's Director of Government Affairs and Programs at klayton@childrens-coalition.org or 916-443-7086.

Sincerely,

Carlos Lerner, MD
Board President
Children's Specialty Care Coalition

CALIFORNIA COALITION FOR CHILDREN'S SAFETY & HEALTH

June 30, 2023

Senator Richard Roth, Chair
Senate Business, Professions & Economic Development
1021 O Street, Room 3320
Sacramento, CA 95814

RE: SUPPORT FOR SB 782 (McKinnor)

Dear Senator Roth,

We are writing to request that you consider supporting AB 782 (McKinnor) to ensure that pharmacies throughout California can continue to offer flavoring of medications prescribed for toddlers and children.

Pharmacies in California have been flavoring children's liquid medications for decades to help children take their prescribed medicines by enhancing palatability. Flavoring of children's medications is authorized pursuant to Article 4.5, Section 1735 of Board of Pharmacy regulations which states:

> (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."

This has been in Board regulations since 2017.

It is estimated that at least six million children have had their medications flavored in California without a single incident of harm coming to a child. Moreover, we estimate that some 180 million medications have been using flavoring systems across the country, again with zero reported incidents of harm. 49 states (including California) currently exempt flavorings from all compounding requirements or merely require documentation of flavor being added to medications, thus allowing pharmacies to provide this basic pharmacy service free of unnecessary regulatory red-tape.

Unfortunately, the California Board of Pharmacy (Board) is poised to reverse its longstanding position by adopting new regulations that would in-effect repeal Section 1735 above. This is an unintended consequence of the passage of AB 973 (Irwin, Chapter 184) in 2019, which directs the Board to require the compounding of drug preparations to be consistent with standards established by the United States Pharmacopeia-National Formulary (USP).

Although AB 973 was specific to compounding, it had nothing to do with flavoring of children's medications. Instead, the argument was that a multistate outbreak of fungal meningitis where unsafe sterile compounding of spinal injections resulted in numerous deaths demonstrated the need for consistent regulatory standards.

The California Board of Pharmacy argues its hands are tied as AB 973 requires the board to adopt the most recent version of USP standards relative to compounding that would have the effect of repealing Section 1735 of the board's current regulations which exclude flavoring from the definition of compounding.

If Section 1735 is repealed it would require thousands of retail pharmacies in California to essentially qualify as a "compounding pharmacy "in order to continue flavorings children's medications. Under current regulations "compounding pharmacies" are the exception, not the rule. For example, there are only three compounding pharmacies in the greater Sacramento area. Compounding pharmacies are even rarer in rural and underserved areas of the state.

Qualifying as a compounding pharmacy is a time-consuming and expensive proposition. It is almost certain that all but a few pharmacies will simply stop flavoring children's medications, rather than incur the time, training, and expense of becoming a compounding pharmacy.

Without urgent legislative action to exempt flavoring of children's medications, California parents will be left to again deal with the difficulties of getting their toddlers and children to take unpalatable 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.

AB 782 simply codifies the Board's existing exemption and position on compounding (found above) so that pharmacies can continue to flavor children's medicine.

Thank you.

Catherine Barankin

Catherine Barankin
Executive Director
428 J Street, Fourth Floor
Sacramento, CA 95814
(916) 447-7341

JORDAN'S
GUARDIAN ANGELS

June 29, 2023

Senator Richard Roth, Chair
Senate Business, Professions & Economic Development
1021 Q Street, Room 3320
Sacramento, CA 95814

RE: SUPPORT FOR AB 782 (McKinnor)

Dear Senator Roth,

As you are aware, Jordan's Guardian Angels is sponsoring impactful research into Jordan's Syndrome, which may open doors to assist with many other diseases. In addition, we have a network of over 380 families who have special needs children who are challenged with the need to administer a variety of life saving medications to children who face many physical and intellectual disabilities.

We are writing to request that you consider supporting AB 782 (McKinnor) to ensure that pharmacies throughout California can continue to offer flavoring of medications prescribed for toddlers and children. **This assistance is often critical to assure special needs children receive the medications that are so important to their well being.**

Pharmacies in California have been flavoring children's liquid medications for decades to help children take their prescribed medicines by enhancing palatability. Flavoring of children's medications is authorized pursuant to Article 4.5, Section 1735 of Board of Pharmacy regulations which states:

(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."

This has been in Board regulations since 2017.

Unfortunately, the California Board of Pharmacy (Board) is poised to reverse its longstanding position by adopting new regulations that would in-effect repeal Section 1735 above. This is an unintended consequence of the passage of AB 973 (Irwin, Chapter 184) in 2019, which directs the Board to require the compounding of drug preparations to be consistent with standards established by the United States Pharmacopeia-National Formulary (USP).

Although AB 973 was specific to compounding, it had nothing to do with flavoring of children's medications. Instead, the argument was that a multistate outbreak of fungal meningitis where unsafe sterile compounding of spinal injections resulted in numerous deaths demonstrated the need for consistent regulatory standards.

The Senator Hotel, 1121 L Street, Suite 100, Sacramento, CA 95814 / Phone 916 441-6222 Fax 916 441-2024

JORDAN'S
GUARDIAN ANGELS

Qualifying as a compounding pharmacy is a time consuming and an expensive proposition. It is almost certain that all but a few pharmacies will simply stop flavoring children's medications, rather than incur the time, training, and expense of becoming a compounding pharmacy.

Without urgent legislative action to exempt flavoring of children's medications, California parents will be left to again deal with the difficulties of getting their toddlers and children to take unpalatable prescribed medications. **This becomes a particular hardship for special needs children**. 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.

AB 782 simply codifies the Board's existing exemption and position on compounding (found above) so that pharmacies can continue to flavor children's medicine. We strongly urge you to keep special needs children in mind and give them the special attention they deserve by supporting AB 782.

Sincerely,

Joe Lang

Joe Lang

Chair

The Senator Hotel, 1121 L Street, Suite 100, Sacramento, CA 95814 / Phone 916 441-6222 Fax 916 441-2024

June 22, 2023

The Honorable Senator Richard D. Roth
Chair, Senate Committee on Business, Professions & Economic Development
1021 O Street, Room 3320
Sacramento, CA 95814

Subject: AB 782 (Lackey) – Pharmacies: Compounding. Position: Support

Dear Senator Roth:

The California Community Pharmacy Coalition (CCPC) supports AB 782 (Lackey), which would amend Section 4126.8 of the Business and Professions Code to specify that compounding does not include 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.

The CCPC is a project of the California Retailers Association and was formed to promote the positive impacts community pharmacies have within California's healthcare system by working on legislation and regulations that will expand access opportunities for community pharmacy services including in hard to reach, under-served areas where Californians often have very limited options for healthcare.

Medication flavoring takes place at more than 3,000 community pharmacies in California and nearly 40,000 pharmacies across the country each year as a point-of-care service focused on improving the taste and palatability of children's liquid medication. In the past 27 years, there have been no reported events of patient harm or death from using medication flavoring. Flavoring has been a non-controversial issue for decades.

Recently, there has been a development by the California Board of Pharmacy that has created some ambiguity in the regulatory language related to flavoring. This is raising concerns among pharmacists, parents with children who won't take the medicine they need without the flavoring and the entire pharmacy community.

A compounding pharmacy is a specific type that makes custom medications for people with highly specific medication needs and requirements. Compounding pharmacies must adhere to different regulatory requirements than standard pharmacies. For over 10 years, California's state regulators have determined that the act of flavoring does not rise to the level of traditional compounding in any practical way. And in that time, millions of medications have been flavored without any harm coming to a child.

Additionally, 48 out of 50 State Boards of Pharmacy do not regulate flavoring as compounding. 98% of children between the ages of zero to 11 live in a state that does not consider flavoring of medications to be compounding. This currently includes the six million children under the age of 11 living in California.

California's community pharmacies provide a simple and safe service to flavor medications for their patients who may otherwise not be able to take the medication they need, especially in the case of parents with small children. Without this bill, this new regulation under consideration by the California State Board of Pharmacy will take away this essential service that pharmacists all

over the state- including in rural, hard to reach and underserved areas- can offer to sick children and worried parents alike.

For these reasons listed above, the CCP Coalition supports AB 782 (Lackey) and urges your aye vote. If you have any questions, please reach contact 916-443-1975.

Respectfully,

Sarah Pollo
Director, Communications & Public Affairs
California Community Pharmacy Coalition/California Retailers Association