to the Board's current regula n since 2010, or even a (e r the enactment of AB 973, and it would not be the case going forward. When AB 782 passes, it will remove flavoring from the state's e finin n of compounding and thus, any requirements applicable to non-sterile compounders under USP 795 will not apply. It is wo no g that the 503A language has been in statute since 1997. Nothing has changed.

Addi nally, 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 prac e outside the scope of compounding. This argument is misplaced. **Currently, 49 out of 50 State Boards of Pharmacy do not regulate flavoring as compounding to USP standards.** In fact, many state boards of pharmacy throughout the United States have explicitly carved out medica n flavoring from their state's defini n of what cons tutes drug compoundi ng in order to prevent flavoring from being considered compounding.

As you will see on the a ached map, more than hal f of the states have taken efforts to expressly clarify that medica n flavoring does not cons tute compounding in their state, either through rule or guidance. The remaining states, aside from one (Washington), have informal policies that effec ely carves out medica n flavoring from its defini n of compounding or they simply require record-keeping when medica ns are flavored, thereby allowing pharmacies to perform medica n flavori ng without having to meet USP's onerous nonsterile compounding requirements. One state, Illinois, enacted a law that specifically exempts medica n flavoring from the defini n of "compounding." **There has been no conflict or risk of enforcement by FDA or accreditors**. The result has been en ely posi e for publ ic health and pa nt access to medicine.

Status quo 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 poten al cost to the state. Educa n of pharmacists on the new requirements, to enforcement ac s to ensure compliance are the most obvious. If pharmacies choose to comply with the onerous USP requirements the board has proposed (see a ached for the complete list of USP 795 requirements), pharmacists will be asked to do more for a service they currently provide without issue.

Board members expressed concern that licensees would be confused should AB 782 pass and unclear on whether addi nal documenta n would be required. It appears the Board may be confused as to what the language in AB 782 does – it amends the requirement in AB 973 to EXEMPT flavoring from the requirements of USP 795 (whether documenta n as the Board asserts, or more as we have illustrated with the a achment). There are no other laws -- with the excep n of AB 973 -- requiring California to enforce USP 795, as stated by Board Member Serpa during the discussion on July 18th at the commi e hearing. A licensee would con ue to operate with flavoring as they do now and have for decades. Where is the confusion about the **status quo**? What WOULD be more confusing for licensees would be having to adopt numerous new requirements and now call a doctor for a prescrip n for flavor should USP 795 apply.

The recommendation to oppose AB 782 is a stance that supports limiting access to these patients that would otherwise not take their medicine. You've stated that you are not making flavoring illegal and that the use of flavoring agents is important to ensure pa nt adherence. But to off er flavoring a pharmacy would have to have a prescrip n from a doctor and suddenly be subjected to non-sterile compounding standards to do so. It is well known that most of the 3,000 community and independent pharmacies in California that currently offer flavoring cannot or will not take on the addi nal cost and regulatory burden to convert. That is the prac al effect of opposing AB 782. You will then be forced to regulate to death a service that does no harm, only good as many of you have said. With far fewer compounding pharmacies statewide, parents and their children will simply be denied access to flavoring. **That denial of access will be even more pronounced in rural and underserved areas**

of the state and for those children with severe or chronic medical conditions or special needs who need to take medication daily or multiple times a day.

The Board of Pharmacy is tasked with protecting and promoting the health and safety of Californians. **By opposing a bill that protects the status quo, without any reason for this policy shift, the Board threatens to do damage to public health by unnecessarily choosing to restrict access to flavored medicine.** If children do not take their medicine, they stay sick longer, are contagious longer, frequently have to go back to the doctor's office, and parents will have to stay home from work longer. California has never been shy in taking affirmative pro-consumer positions, even when there is a conflict of law and risk of federal enforcement. Why start now at the expense of children's health?

For all the above-stated reasons, the Board should stand with the children and California's public health to support AB 782.

Please do not hesitate to contact our office should you have any questions or would like additional information.

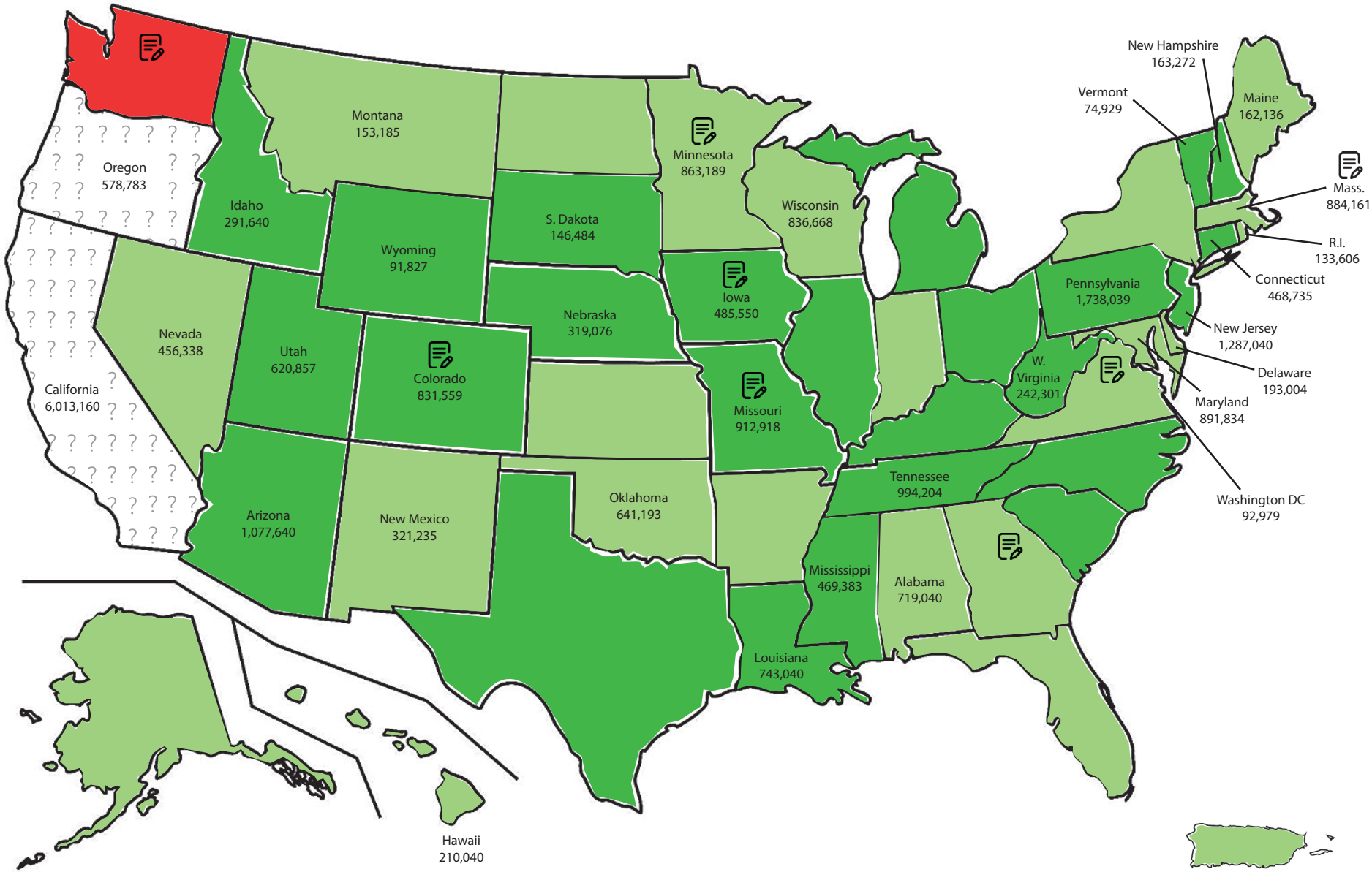
Thank you.

Attachments

ANTICIPATED **BOARD OF PHARMACY POSITIONS** TOWARDS **FLAVORING** ON NOVEMBER 1, 2023

(STATUS AS OF July 26, 2023)

- Flavoring will not be considered compounding per statute, BOP rule or published FAQ.
- Flavoring will not be considered compounding per BOP guidance and/or use of enforcement discretion OR only record-keeping will be required.
- Flavoring will be regulated as compounding with full adherence to USP 795 standards
- ? Uncertain at this time
- States that require documentation for flavoring



Data Source: Population Division, U.S. Census Bureau

(Numbers reflect how many children between the ages of 0-11 live in each State)

Should AB 782 NOT PASS, the following NEW requirements will be imposed on pharmacies who choose to continue flavoring children's medications in California.

USP 795 Requirements – 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 – 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.

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