From: Shanna O'Connor < soconnor21@yahoo.com >

Sent: Friday, July 11, 2025 5:50 PM

To: SD Pharmacy Board < PharmacyBoard@state.sd.us Subject: [EXT] Comments on proposed Board rules

Good evening,

Please see below for comments related to the proposed board rules (5/14/25). I am making these comments and suggestions as an individual citizen of South Dakota. Thank you for your time in reviewing these suggestions and for your work and expertise in administering them.

Cheers,

Shanna

- 1. 20:51:02:01 (4) should be removed entirely as residents and fellows would be covered under 3
- 2. 20:51:02:07—Why is a separate form required for each experience? A single affidavit for all intern hours (with requirement to produce evidence upon request) should be sufficient. Removal of this requirement would remove unnecessary administrative burden.
- 3. 20:51:05:22—5% rule should be amended to allow pharmacies to transfer distribute, or sell medications for emergency medical reasons, including public health emergency declarations by federal or state officials, medication shortages, and individual patient needs. This language is supported by NABP and medication shortages are a known issue in SD that is unlikely to go away in the next decade but is projected to get worse—imposing a restriction on how much pharmacies are able to help each other meet the challenges of medication shortages imposes unnecessary administrative burden and introduces roadblocks for provision of optimal patient care.
- 4. 20:51:13:05: Reference to stapled/prescription bag in (d) should be modified to be more inclusive of all medications (some don't fit in a bag, not all processes for dispensing mandate a bag as the end transportation pathway) and instead focus on the PHI element (PHI should be concealed such that the only information visible is the name of the patient and, in the case a patient designee is picking up the prescription, the name of the patient designee; (g) reference to 'bags' should be removed as this is a limiting element
- 5. 20:51:28:02.02: Requirement for certification of technicians should be removed; so long as the technician is appropriately trained, additional certification does not influence their ability to correctly administer an immunization. Inclusion of this requirement presents a barrier to access for patients and could negatively impact the health of the public.
- 6. 20:51:29:19: Restricting ratio for community pharmacy but not other pharmacy practice is counter-intuitive and impedes practice in communities. The ratio should either be removed entirely or changed to have less specific language that is appropriate for all areas of practice (PIC determines for all areas of practice)
- 7. 20:51:30:12 Pharmacy technicians working in remote areas of the state may be less likely to be certified; rather than certified, the language should be changed to 'appropriately trained as determined by the PIC' to support access to pharmacy services in remote areas of the state

8. allow pharmacies to transfer, distribute, or sell medications for emergency medical reasons, including public health emergency declarations by federal or state officials, and individual patient needs

Shanna K. O'Connor, PharmD, BCACP

From: Chad Baker < CBaker@flavorx.com >

Sent: Friday, July 11, 2025 11:46 AM

To: SD Pharmacy Board < PharmacyBoard@state.sd.us>

Subject: [EXT] Comments for the July 17 Board of Pharmacy Meeting

Good Morning,

Please accept these written comments for the Board's consideration at the July 17 meeting. Thank you!

Chad

July 11, 2025

Executive Director: Tyler Laetsch, PharmD.

South Dakota Board of Pharmacy

4001 W Valhalla Blvd. Suite 106

Sioux Falls, SD 57106

Dear Mr. Laetsch & Members of the South Dakota Board of Pharmacy,

Thank you for providing me with the opportunity to submit written comments to the Board and for your consideration of my submission. I am writing requesting clarification on whether the Board of Pharmacy intends to subject the longstanding practice of medication flavoring in South Dakota to the new USP 795 non-sterile compounding requirements.

A September 2023 version of the proposed changes to Articles 20.51.31 contained a clause stating "the addition of a flavoring agent to a drug product" was excluded from USP requirements. Since that language is no longer contained in the draft rules under consideration, many of our pharmacy partners in South Dakota have taken this to mean the Board plans to fully enforce USP 795 standards on medication flavoring. I hope this is not the case. The ramifications of such a policy will not be compliance from your licensees but rather removal of this valuable service from their

pharmacies. The new USP 795 standards go too far when it comes to such a simple, proven-safe pharmacy service that has been provided to South Dakota families for decades without any reported incidents of harm. For a service that most pharmacies provide to their customers to improve pediatric compliance with little to no regard for profit, the burden to comply is too high.

For some perspective, 48 of 50 State Boards of Pharmacy, plus Washington D.C. and Puerto Rico, provide some form of relief from USP standards when it comes to medication flavoring. Many explicitly carve flavoring out from compounding, while others exercise enforcement discretion. In the two states that now require full compliance with the new USP non-sterile compounding standards when flavoring, California and Washington, the number of pharmacies offering the service to customers has dropped from thousands to a mere handful.

Again, I hope it is not the intention of the Board of Pharmacy to effectively force the removal of the medication flavoring service from the many pharmacies who currently offer it in South Dakota. There are proven ways to place safety guardrails around the practice of medication flavoring without burdening pharmacies with unnecessary and unhelpful regulatory requirements. If I can be of any assistance in providing language adopted by other State Boards of Pharmacy, I am more than happy to do so.

I appreciate you taking the time to read this letter and for your consideration. Your clarification of the Board's position on the subject is critically important.

Chad Baker Senior Vice President, Government Relations FLAVORx, Inc. cbaker@flavorx.com (443) 223-2710