

FORM 10

MINUTES OF PUBLIC HEARING South Dakota Board of Pharmacy

The South Dakota Board of Pharmacy convened at 2:04 p.m. CDT on July 17, 2025, at 4001 W. Valhalla Blvd., Ste. 202, Sioux Falls, SD 57106.

The purpose of the meeting was to conduct a public hearing on the proposed rules of South Dakota Board of Pharmacy numbered §§ 20:51:01, 20:51:02, 20:51:04, 20:51:05, 20:51:06, 20:51:07, 20:51:13, 20:51:14, 20:51:15, 20:51:16, 20:51:17, 20:51:19, 20:51:25, 20:51:27, 20:51:28, 20:51:29, 20:51:30, 20:51:31, 20:51:33, 20:51:36 and 20:67:02.

Hearing Officer: Ashley Hansen, South Dakota Board of Pharmacy President

Members of the Board in Attendance: Shane Clarambeau (virtual), Ashley Hansen, Cheri Kraemer, Tom Nelson (virtual), and Curt Rising (Virtual)

Others in Attendance: Tyler Laetsch, Melissa DeNoon, Jenna Heyen, Elizabeth Hallway, Lee Cordell, Carol Smith, Beth Windschitl, Jeremy Daniels, Jessica Strobl, Austin W., Victoria Kroeger, Amanda Bacon, Emily Van Klompenburg, Joe Bergsmith, Logan May, Sarah Watson, Riley Williams, Deeb D. Eid, and Sarah Cronin.

Roll Call / Approval of Agenda

The Hearing Officer and Presiding Chair, Ashley Hansen, called the meeting to order at 2:04 pm, explained the reason for the Rules Hearing, and reviewed meeting protocol. Voice roll call was taken, mission statement read, a quorum confirmed, and introductions completed. The only item on the agenda is the Rules Hearing

Motion to approve the agenda was ratified, Kraemer/Rising/Unanimous

Rules Hearing Presentation of Proposed Rules

Board Executive Director Tyler Laetsch explained the rules promulgation process, activities completed by the board, and presented a synopsis of the amended draft rules as enumerated in the agenda (Article 20:51 and Article 20:67).

Oral Testimony

- Jeremy Daniels
 - Avera McKennan Hospital, South Dakota State University faculty, South Dakota Pharmacist Association (SDPhA) representative
 - Comments were based on review of the previous version of the document, not the final version of the document posted on the Boards and Commission site.
 - Proponent
 - South Dakota Resident
 - 20:51:01:04 Test Total Scale Score not less than 75 is passing; scores are now Pass or Fail, numerical score not shared by NABP with licensing boards.
 - 20:51:06:02.01 concern addressed in final document
 - 20:51:06:03 concerns addressed in final document
 - 20:51:06:08 concern repealed and is in law

- 20:51:13:02.04 Compliance packaging rule does not appear to allow for a person to bring their medications to a pharmacy to have medications re-packaged. Requested clarity of the rule to align with the practice in the field
 - 20:51:13:06 Medication dispensing at the clinic must be done by the prescriber. Request clarity of the rule to align with the practice in the field
 - 20:51:15:10 Clarification of terms: “pharmacist-in-charge” and “pharmacist owner”
 - 20:51:30:12 What is special about a remote pharmacy that requires a certified technician vs a registered technician? Respondent interprets the rule as written to mean interns could supervise technicians.
 - Suggested changes, clarification, and general support for modifications
 - Agency Discussed
 - Agency Action – No Change
- Victoria Kroeger
 - Walgreens, Pharmacy Affairs Representative
 - Proponent or Opponent – Undeclared
 - Unknown
 - 20:51:06:02
 - Clarification regarding the requirement that the pharmacy notify the board within ten days of a pharmacist-in-charge change, with non-compliance resulting in license voidance. Suggest a requirement change to a 30-day transfer timeline.
 - Suggested changes, clarification, and general support for modifications
 - Agency Discussed
 - Agency Action – No change

Written Testimony

- Chad Baker
 - FLAVORx, Inc., SVP, Government Relations
 - Proponent or Opponent – Undeclared
 - FLAVORx, Columbia, MD
 - July 11, 2025
 - 20:51:31
 - Removal of language “the addition of flavoring agent to a drug product” from the proposed draft rules. Clarification (removal of the language from the draft is interpreted to mean the board plans to fully enforce USP 795 standards on medication flavoring, and the submitter is seeking some form of relief from the USP standards). Requested that flavoring be excluded from compounding standards. Removal could limit access to flavoring for pediatric medications.
 - Agency Discussed – Law and Rule to site USP 795 does not allow for any carve-outs.
 - Agency Action – No Change
- Shanna O’Connor
 - Private citizen
 - Proponent or Opponent – Undeclared
 - Residence of South Dakota
 - July 11, 2025

- 20:51:02:01(4); 20:51:02:07; 20:51:05:22; 20:51:13:05; 20:51:28:02.02; 20:51:29:19; and 20:51:30:12
- Remove technician certification requirement and ratio restrictions, requirement of separate affidavit form per experience, amend 5% rule to allow medication sales for emergency reasons, modify bag dispensing mandate and transfers, and eliminate multiple intern affidavit requirement.
- Suggestions, changes, clarification, and general support with modifications
- Agency Discussed
- Agency Action – No Change

Discussion

1. FLAVORx: Unable to change as we cite USP 795 in the rule, and we cannot cite the document and carve certain items out.
2. 20:51:05:02 The 5% Rule allows pharmacies to sell up to 5% of medications; if more is sold entity is functioning as a wholesaler. Public health emergency exclusion in SDCL 36-11A-2(5) is an excluded transaction; therefore, no change is warranted.
3. 20:51:02:07 Use of one affidavit for all sites. A foreign grad intern may work at multiple pharmacy locations, so one affidavit to assess activity/performance at all sites does not work. One affidavit per site is still needed.
4. 20:51:08:02.02 Technician certification required for immunization and telepharmacy employment. The requirement is still appropriate.
5. 20:51:29:19 Eliminate retail pharmacy ratio. This request has been brought forth each year with rule change hearings.
6. 20:51:01:04 Pass versus Fail licensure exam scores. Will contact NABP to inquire if an actual score is determined.
7. 20:51:13:02.04 Repackaging if the patient brings their medication to the pharmacy for repackaging rule would not allow for repackaging. The board has a policy statement that allows for repackaging.
8. 20:51:13:06(5) E-Kits/Starter Packs dispensed at a hospital or clinic must be dispensed by the provider. Clarification provided and no change needed.
9. 20:51:30:12 Supervision of certified technician at telepharmacy (remote) site; technician to complete a total of 1,000 hours of experience, of which 500 hours must be at the remote location. Supervision by a pharmacist at the central pharmacy or remote pharmacy location is required. A certified technician cannot work independently until the 1,000-hour requirement is met. Changed wording on the 500 hours must be done at the central pharmacy or remote pharmacy.
10. 20:51:06:02 PIC change transfer must be completed in ten days. Allows a pharmacy to operate without a designated PIC for ten days. Can designate a "temporary" PIC. Operating for 30 days without a designated PIC / temporary PIC is problematic. Controlled substances are counted with each transfer. The pharmacy needs to have someone accountable. Ten-day requirement maintained.

Summary of LRC Comments/Changes

1. 20:51:04:01(2) Reciprocity fee cannot exceed \$150.00. Board recommends elimination of \$35.00 initial certification fee charged for the pharmacist reciprocity application.
2. 20:51:06:02 \$50 fee for a pharmacist-in-charge change. Board to seek clarification as the PIC change is being potentially confused with the pharmacy license transfer. Board recommends keeping as written.
3. 20:51:06:09 Describes the effect on pharmacy activity upon pharmacist owner death and pharmacy license transfer. Board recommends no change.

4. 20:51:06:10 Describes the ability of a pharmacy to continue operations in the absence of a pharmacist. Board recommends no change.
5. 20:51:07:03 Minimum equipment needed in a pharmacy. List of specific equipment necessary to provide pharmacy services. The rule passed last year as currently written. Board recommends no change.
6. 20:51:13:05 Authorizes use of remote pick-up site for prescription medications. Accept language for pick-up sites. Previously addressed in a guidance document. LRC questioned the board's authority to make a rule; no statutory basis. Board recommends no change.
7. 20:51:13:06 Authorizes the use of prescription medication starter packs (a short-term supply of medication) provided by medical clinics and hospitals to a patient. Board recommends no changes.
8. 20:51:33 Established complaint process; section repealed due to uniform complaint procedure codified in 2021. Accept the LRC recommendation to repeal.

Summary of Changes to Proposed Rules Because of the Public Hearing or Comment

- ARSD §§§§ 20:51:01, 20:51:02, 20:51:04, 20:51:05, 20:51:06, 20:51:07, 20:51:13, 20:51:14, 20:51:15, 20:51:16, 20:51:17, 20:51:19, 20:51:25, 20:51:27, 20:51:28, 20:51:29, 20:51:30, 20:51:31, 20:51:33, 20:51:36 and 20:67:02.
- Description of Changes
 - Accept LRC form and style comments and all of the rules as amended in the discussion.
 - Strike the \$35.00 initial certification fee charge for pharmacist reciprocity application
- Reason for Changes – After discussion and public and written comments, it was reviewed and amicably agreed to modification/clarification of the above rule chapters.

A motion to accept all rules based on discussion, all rule changes suggested by LRC as presented, and changes suggested in comments was ratified (Kraemer/Rising/Unanimous)

Adjournment: (Kraemer/Nelson) 4:12 p.m.

Respectfully submitted,

Tyler J. Laetsch
Executive Director
South Dakota Board of Pharmacy