Windschitl, Beth

From: Windschitl, Beth
Sent: Tuesday, April 9, 2024 12:43 PM
To: Shanard-Koenders, Kari; Laetsch, Tyler
Subject: FW: [EXT] BOP - Proposed Rules
Attachments: BOP.pdf; Rule Amendments.pdf

Forwarding rules comments received in the general email box.

Sincerely,

Beth Windschitl
Senior Secretary
South Dakota Board of Pharmacy
4001 W. Valhalla Blvd, Ste 106
Sioux Falls, SD 57106
beth.windschitl@state.sd.us

From: Lindsey Riter-Rapp <L.Riter-Rapp@riterlaw.com>
Sent: Tuesday, April 9, 2024 11:56 AM
To: SD Pharmacy Board <PharmacyBoard@state.sd.us>
Cc: Amanda Bacon <amanda@sdpha.org>; Robert Riter <R.Riter@riterlaw.com>
Subject: [EXT] BOP - Proposed Rules

Dear Members of the Board of Pharmacy,

You will find attached herein the following documents for your consideration during the public hearing that will be held by the Board of Pharmacy on Friday, April 12, 2024.

1. Written comments from SDPhA's President Jessica Strobl dated April 9, 2024; and
2. Draft Amendments from SDPhA (Rules 20:51:19:06 and Rule 20:51:29:07)

We intend to participate in the public hearing scheduled for this date and will be available to answer any questions the board might have relative to the written comments and proposed amendments. We appreciate your consideration of the same.

Sincerely,

Lindsey Riter-Rapp

Cc'd

Amanda Bacon – Executive Director SDPhA

Robert Riter

April 9, 2024

South Dakota Board of Pharmacy
4001 W. Valhalla Blvd., Suite 106
Sioux Falls, S.D. 57106
pharmacyboard@state.sd.us

Re: Proposed Administrative Rules

Dear Members of the Board of Pharmacy:

On behalf of the South Dakota Pharmacists Association, we would like to submit the following written comments in response to the proposed rules that will be considered by the Board during its public hearing on April 12, 2024.

A. 20:51:14:01 - The most notable modification is the increase in the annual certification renewal fee for pharmacists from $125 to $150. We have concerns with increasing this fee given the recent denial of funding for services provided by SDPhA. While we recognize the financial position the Board finds itself in, we are concerned with any effort to shift the burden to fund this shortfall to pharmacists through both elimination of their funding and an increase to their fees. Further, it would appear appropriate that before any increase is considered, further inquiry be made regarding the nature of the funding shortfall and the reasons therefor.

B. 20:51:19:03 - It appears the hours of training required for a pharmacist to administer immunizations is being reduced from two hours to one hour. We are interested in understanding the basis for this modification.

C. 20:51:05:15.01 - It would require identification for controlled drug prescriptions. If such a requirement is going to be implemented, we think it is important to be consistent. Hence, we would recommend that identification be required for everyone, known or unknown, or there is a "known to pharmacy staff" option available.

D. 20:51:19:06 - It authorizes the use of continuing education hours obtained in another state if the program has been approved by that state's board of pharmacy. We certainly support this modification but believe it appropriate that any coursework approved by the Accreditation Council for Pharmacy Education ("ACPE") also not require separate Board approval. *See*, proposed amendment to Rule 20:51:19:06.

E. 20:51:24:02(5) and 20:51:24:04- These provisions would increase the length of time a pharmacy is required to retain information in the patient record system from one year to at least two years from the date of the last entry in the record. We are interested in learning the basis for the extension of mandatory retention time.

F. 20:51:28:02.02 - This section would authorize pharmacy technicians to administer immunizations under certain circumstances. We certainly support this effort but want to be certain the proper statutory authority exists for implementation of this rule.

G. 20:51:29:03 - It appears the modification is intended to broaden the scope of those individuals that would be eligible to obtain a pharmacy technician registration. While generally supportive, we would like further clarification regarding the intent of this change and the efforts to ensure the health and safety of the practice is maintained.

H. 20:51:29:07. Finally, it is unclear in reviewing the proposed modification to this rule whether the intent is to eliminate the fee for renewal of a pharmacy technicians. We would have several concerns with such elimination. First, it would be contrary to the provisions of SDCL 36-11-11(13) that contemplate an annual registration renewal fee not to exceed $30. It would also appear to be an inopportune time to eliminate this fee given the contemplated increase to the renewal fee for pharmacists. Further, it would seem appropriate for the board to recover any fees incurred for the time and expense in processing each renewal. Finally, we believe the renewal process preserves and promotes the efficacy of the practice of pharmacy and thus it is important to maintain this

provision. Hence, we believe it appropriate to make certain that the $25 fee is also required with a renewal. *See*, proposed amendment to Rule 20:51:29:07.

We would like to end by saying that we find broad general support for many of the modifications offered, especially regarding legend drug dispensing in 20:51:05:20, as well as simplification and streamlining processes for compounding through the repeal of the included compounding rules, as well as additions that simply align with United States Pharmacopia (USP) compounding standards and requirements.

We look forward to the opportunity to provide further public input regarding the proposed rules at the upcoming public hearing. If you have any further questions in advance thereof, please let us know.

Thank you.

Very truly yours,

BY:

Jessica Strobl
President, SDPhA

Cc: Amanda Bacon
Robert Riter
Lindsey Riter-Rapp

20:51:19:06. Continuing education ~~from other states~~. The ~~Board of Pharmacy~~ board may accept ~~comparable~~ continuing education hours obtained in any other state, if the program is approved by the other ~~state boards~~ state's board of pharmacy. The board may also accept any continuing education hours that are certified by the Accreditation Council for Pharmacy Education ("ACPE"), ~~and the South Dakota Board of Pharmacy~~.

Source: 4 SDR 54m effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-10,25-11-11(1).

Law Implemented: SDCL 36-11-23.2.

20:51:29:07. Registration application form - fee. The application form for initial registration or renewal as a pharmacy technician shall include ~~the following~~:

(1) ~~Information sufficient to identify the applicant including~~ The applicant's name, address, phone number, date of birth, gender, ~~and~~ social security number, and email address;

(2) Work experience; ~~and~~

(3) Current and past places of employment; and

(4) A non-refundable twenty-five dollar fee.

Source: 31 SDR 35, effective September 19, 2004.

General Authority: SDCL 36-11-11(1)(13), ~~36-11-11(14)~~.

Law Implemented: SDCL 36-11-11~~(14)~~(13).

Shanard-Koenders, Kari

From: Heins, Jodi <Jodi.Heins@sdstate.edu>
Sent: Monday, April 8, 2024 4:25 PM
To: SD Pharmacy Board
Cc: Shanard-Koenders, Kari; Hansen, Daniel
Subject: [EXT] Proposed Rules changes

South Dakota Board of Pharmacy,

This letter is to provide suggestions on the proposed rule changes by the board. The suggested changes are intended to provide clarity to ACPE approved continuing education activities as approved continuing education by the board and not requiring additional reporting of credit to the board. Suggestions are provided below in yellow.

20:51:19:14 - This section is not being edited. It is unclear who the "advisory council on continuing education" is and it may be helpful to provide clarification.
20:51:19:14. Attendance by board or council members. Any member of the South Dakota Board of Pharmacy or advisory council on continuing education shall have the right to attend and supervise any continuing education program.

20:51:19:03 – The statement added would provide additional clarification on ACPE approved education that is designated immunization specific.
20:51:19:03. Hours required. To qualify for ~~relicensure, an active~~ certificate of registration renewal or reinstatement, a pharmacist must successfully complete ~~12~~ twelve hours of continuing education. The ~~12~~ twelve hours of continuing education required each year for ~~relicensure~~ renewal must be completed within the ~~24~~ twenty-four months before the pharmacist's certificate of registration expires. ~~When~~ If a pharmacist applies for yearly renewal of the pharmacist's certificate of registration pursuant to SDCL 36-11-23, the pharmacist ~~must report completed continuing education hours on a form supplied by the board~~ shall have completed the required hours. If the pharmacist has a certification to administer immunizations, the pharmacist shall complete one hour of continuing education related to immunizations, which may be one of the required twelve hours. Activities that qualify for the immunization requirement by Accreditation Council for Pharmacy Education (ACPE) approved continuing education will have the continuing pharmacy education (CPE) topic designator of "06" followed by the letter "P" at the end of the universal activity number.

20:51:19:04. – The highlighted statements added would provide clarity to ACPE approved continuing education and board approved continuing education.
20:51:19:04. Hours defined. The hourly value for continuing pharmacy education (CPE) credit is defined as the measurement of value applied to a particular Accreditation Council for Pharmacy Education (ACPE) accredited continuing pharmacy educational activity as assigned by the Accreditation Council for Pharmacy Education (ACPE) provider or as assigned by the ~~Board of Pharmacy~~ board for non-ACPE accredited programs approved by the board relative to maintaining the competency of a registrant.

20:51:19:06. – The statements added would provide clarity on ACPE approved continuing education as not needing additional approval from the board.
20:51:19:06. Continuing education from other states. The ~~Board of Pharmacy~~ board may accept ~~comparable~~ continuing pharmacy education hours obtained in any state, if the program is approved by the other ~~state~~

~~boards~~ state's board of pharmacy~~, and the South Dakota Board of Pharmacy~~. Continuing pharmacy education (CPE) activities that carry the seal of the Accreditation Council for Pharmacy Education (ACPE) – accredited provider will automatically qualify for CPE hours.

20:51:19:08. – This section is currently recommended for repeal by the board. The suggestions could be considered to also further clarify ACPE and non-ACPE approved continuing education and not being repealed. It would also provide clarity on the quality expectations of non-ACPE approved continuing education.

20:51:19:08. ~~Different ways of o~~Obtaining accredited continuing education hours.

Accredited continuing pharmacy education (CPE) hours may be obtained from ~~compiled in the following ways~~:

(1) Continuing pharmacy education activities that carry the seal of the Accreditation Council for Pharmacy Education (ACPE) – accredited provider will automatically qualify for CPE hours.

(2) Other sponsors providing a program demonstrating the same quality continuing education standards as those established in the Standards for Continuing Pharmacy Education by the Accreditation Council for Pharmacy Education (ACPE) and approved by the Board of Pharmacy.

~~(1) Cassette and audio visual presentation;~~
~~(2) In-company professional seminars;~~
~~(3) Accredited school of pharmacy continuing education programs;~~
~~(4) Post graduate courses in pharmaceutical sciences;~~
~~(5) Correspondence courses;~~
~~(6) Programs granted continuing education credit by other states;~~
~~(7) Continuing education television series;~~
~~(8) Programs sponsored by professional groups in public health provider services;~~
~~(9) Professional society and association sponsored programs;~~
~~(10) Study groups Repealed.~~

20:51:19:10. – The suggestions provide additional clarification on ACPE approved continuing education and non-ACPE approved continuing education.

20:51:19:10. Program approval. Continuing pharmacy education (CPE) activities that carry the seal of the Accreditation Council for Pharmacy Education (ACPE) – accredited provider will automatically qualify for CPE credit. Non-ACPE accredited activities may qualify for a ~~Each~~ continuing education program ~~must have the approval of be~~ if approved by the ~~Board of Pharmacy~~ board. Sponsors demonstrating the same quality continuing education standards as those established in the Standards for Continuing Pharmacy Education by the Accreditation Council for Pharmacy Education (ACPE) may be approved by the Board of Pharmacy.

Sponsors of non-ACPE accredited CPE activities must apply for approval to the board, on forms furnished by the board, at least ~~30~~ thirty days before the initiation of the course. The board shall send written notice of its approval or disapproval to sponsors.

The board ~~shall~~ must give each approved program an identification number and an hourly value. The board's approval of a program expires at the end of two years.

Each program evaluated must be supported by back-up material, such as a brochure~~, a critique of material covered, a script, or a, cassette or book for a correspondence course~~ and learning objectives.

20:51:19:16. – This is to clarify that only non-ACPE accredited activities would need to be reported to the board.

20:51:19:16. Sponsor to provide list of pharmacists and technicians attending program.

The sponsor of a non-ACPE accredited continuing education program approved by the board shall provide to the ~~Board of Pharmacy~~ board a written or electronic list of the pharmacists and technicians attending within

~~45~~ thirty days after completion of the program or a licensed pharmacist may not use the hours or credits earned to qualify for continuing professional education.

20:51:28:02.02. – The board does not specifically state continuing education requirements for technicians. The national certification of technicians does require 20 hours of continuing education but does not specifically require any content on immunizations. If technicians would be expected to have the continuing education requirements similar to pharmacists this would need to be clarified.

20:51:28:02.02. Qualifications for pharmacy technicians to administer immunizations. A pharmacy technician may administer immunizations if the technician:

(1) Is registered as a certified pharmacy technician in this state;

(2) Has successfully completed an approved immunization training program for technicians;

(3) Is certified in cardiopulmonary resuscitation; and

(4) Is directly supervised by a pharmacist who has a current authorization to administer immunizations in this state.

All technician immunization training and cardiopulmonary resuscitation documents must be kept in the pharmacy and available for inspection at any time.

Please feel free to reach out to me with any questions or clarifications.

Respectfully submitted,

Jodi Heins

SOUTH DAKOTA STATE UNIVERSITY

Jodi Heins, Pharm.D.
Director of Experiential Education/Professor
PGY1 Community-Based Residency Program Director
Office of Experiential Education
Pharmacy & Allied Health Professions
2400 S Minnesota Ave, Ste. 100
Sioux Falls, SD 57105
P: (605) 688-2103
SDState.edu

Windschitl, Beth

From: Windschitl, Beth
Sent: Monday, April 8, 2024 4:54 PM
To: Shanard-Koenders, Kari
Cc: Laetsch, Tyler
Subject: FW: [EXT] Comment on one of the proposed rules

Forwarding comments received in the board general email box.

Sincerely,

Beth Windschitl
Senior Secretary
South Dakota Board of Pharmacy
4001 W. Valhalla Blvd, Ste 106
Sioux Falls, SD 57106
beth.windschitl@state.sd.us

From: Johnson, Laura <laura.johnson1@walgreens.com>
Sent: Monday, April 8, 2024 4:23 PM
To: SD Pharmacy Board <PharmacyBoard@state.sd.us>
Subject: [EXT] Comment on one of the proposed rules

Good Afternoon,

I just have a comments on the rule about the proposed ID requirement for controlled substances.

The rule states "the pharmacy must require a valid government issued form of identification for anyone attempting to purchase or pick up a prescription for a controlled substance listed in SDCL 34-20B, unless the person is known to the pharmacist"

The concern I have is the leeway given for the "unless the person is known to the pharmacist" portion. At Walgreens we all have our regular PICs that work full time in each of the stores but the remainder of our shifts are covered as market pharmacists. I know many patients in my store but if I have a market pharmacist covering for me they will not have that same relationship with the patients that I would. If we are going to have that requirement is should be consistent and that a government issued form of identification should be given for all prescription sales to create consistency instead of giving them the option of not showing the ID if they are "known to the pharmacist". I was at a Walgreens in West Virginia where an ID is required to be shown for all controlled substance pickups and it was easier to just have the patient provide that ID at pickup during all controlled substance pickups and the register would also track the ID that was scanned in case there was any need to figure out who picked up the medication and that seemed like a good system when I was there and it seem to work well in other states.

Hopefully that makes sense,

Thanks,
Laura Johnson
PIC Walgreens #5242

SOUTH DAKOTA STATE MEDICAL ASSOCIATION

Values. Ethics. Advocacy.

2600 W. 49th Street, Suite 100
Sioux Falls, SD 57105-6569
605-336-1965
Fax 605-274-3274
www.sdsma.org

April 3, 2024

South Dakota Board of Pharmacy
4001 W. Valhalla Blvd, Suite 106
Sioux Falls, SD, 57106

RE: Proposed changes to ARSD 20:51

Dear Board Members:

I am writing today on behalf of the South Dakota State Medical Association ("SDSMA"), the professional association of physicians in South Dakota. I am writing to express SDSMA's objection to a specific proposed change to the rules and a suggestion for what SDSMA believes to be a better approach.

Pursuant to SDCL Ch. 36-11, a pharmacist may only dispense drugs pursuant to a prescription from a "practitioner." See SDCL 36-11-2(23), 36-11-2(24), 36-11.2.2. The term "practitioner" is defined as "a person licensed, registered or otherwise authorized by the jurisdiction in which the person is practicing to prescribe drugs in the course of professional practice." SDCL 36-11-2(23).

Several of the proposed amendments change the term "practitioner" to "prescriber." See, e.g., proposed changes to ARSD 20:51:05:15, 20:51:05:20, 20:51:05:22. The term "prescriber" is defined in connection with the prescription drug monitoring program, SDCL 34-20E-1(11), but is not defined in the administrative rules sought to be amended.

In order to avoid the potential for confusion by readers of the rules, SDSMA objects to the change from "practitioner" to "prescriber" and instead respectfully recommends the board use the term "practitioner" throughout its rules except when the context plainly requires otherwise, such as with respect to the prescription drug monitoring program. See ARSD Ch. 20:51:32.

SDSMA is aware the term "prescriber" is used in several rules which are in effect today. See, e.g., 20:51:05:16 and 20:51:05:19. SDSMA encourages the board to adopt a uniform approach to the use of those terms for the reasons stated above and that those rules be amended as permitted by the rule-making process, including in the course of future rule-making by the board.

Thank you for your consideration of SDSMA's comments.

Denise S. Hanisch MD

Denise S. Hanisch, MD, President
South Dakota State Medical Association

Windschitl, Beth

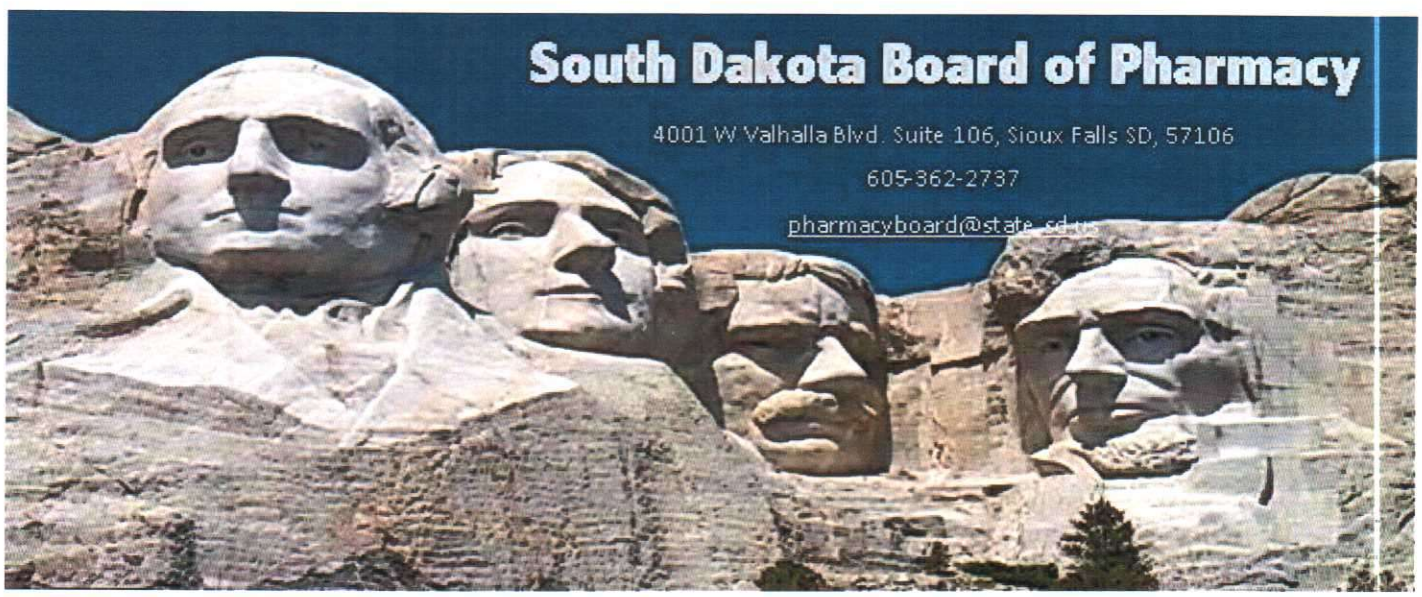
From: Young, Linda
Sent: Monday, March 25, 2024 2:51 PM
To: Shanard-Koenders, Kari
Subject: RE: Notice of Public Hearing to Adopt Rules - April 12, 2024

Kari, reviewed your rules, not sure is you need to have BON/BOME/BOPh meeting for them... to comply with statute. Let me know if so.
Otherwise, one comment or suggested change for your revised rule – not all nurses hold a license in SD due to compact and solutions may be administered by other routes rather than just by injection (IM, SQ, IV) as follows:

20:51:15:07. Preparing a solution. The preparation, by a nurse authorized to practice pursuant to SDCL 36-9, of a solution for administration to a client.

Thanks for consideration,
Linda

From: SD Pharmacy General <SDPHARMACYGENERAL@LISTSERV.SD.GOV> **On Behalf Of** SD Pharmacy Board
Sent: Friday, March 22, 2024 4:30 PM
To: SDPHARMACYGENERAL@LISTSERV.SD.GOV
Subject: Notice of Public Hearing to Adopt Rules - April 12, 2024



South Dakota Board of Pharmacy

Notice of Public Hearing to Adopt Rules

A public hearing will be held in the Hamlet Building, Room 202, 4001 W. Valhalla Blvd, Sioux Falls, SD c April 12, 2024, at 2:00 pm CDT to consider the adoption and amendment of proposed Administrati Rules of South Dakota 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, 20:51:1 20:51:16, 20:51:17, 20:51:19, 20:51:20, 20:51:21, 20:51:22, 20:51:23, 20:51:24, 20:51:25, 20:51:2 20:51:28, 20:51:29, 20:51:30, 20:51:31, and 20:51:36.

The effect of the rules will be to provide for a small fee increase for pharmacists, updated wording, refe ences, compounding standards, and changes in intern and technician vaccine administration standards.

The reason for adopting the proposed rules is to clean up wording and references, add a photo id requir ment for obtaining a controlled substance prescription, set central fill standards, update compounding cha ter to meet new USP Chapters, update intern vaccine requirements and allow trained technician vaccin tions.

Persons interested in presenting amendments, data, opinions, and arguments for or against the propose rules may appear in-person at the hearing, or mail or e-mail them to South Dakota Board of Pharmacy, 400 W. Valhalla Blvd, Suite 106, Sioux Falls, SD 57106 or to Board of Pharmacy email address pharmac board@state.sd.us. **The deadline for the Board to receive any written comments for consideration is Ap 9, 2024.**

After the written comment period, the Board of Pharmacy will consider all written and oral comments it r ceives on the proposed rules. The Board of Pharmacy may modify or amend a proposed rule at that time include or exclude matters that are described in this notice.

For Persons with Disabilities: This hearing will be located at a physically accessible place. Please contact t South Dakota Board of Pharmacy at least 48 hours before the public hearing if you have special needs for whi special arrangements can be made by calling 605-362-2737.

Copies of the proposed rules are attached to this email and may be obtained without charge from:

The Board of Pharmacy website, at pharmacy.sd.gov and/or the Administrative Rules Portal at rules.sd.gov.

Windschitl, Beth

From: Windschitl, Beth
Sent: Tuesday, April 9, 2024 7:49 AM
To: Shanard-Koenders, Kari
Subject: FW: [EXT] Proposed Rules

FYI – Rule change comments received in the board's general email box.

From: Bettinger, Nick <nick.bettinger@cardinalhealth.com>
Sent: Tuesday, April 9, 2024 5:31 AM
To: SD Pharmacy Board <PharmacyBoard@state.sd.us>
Cc: Laetsch, Tyler <Tyler.Laetsch@state.sd.us>
Subject: [EXT] Proposed Rules

SD Pharmacy Board,

I am the PIC and pharmacy manager representing the nuclear pharmacy (Cardinal Health) in Sioux Falls, SD.

I support the Board's proposed rule- **20:51:31:32**. Compounding and hazardous drug handling standards – United States 131 Pharmacopeia compounding standards implemented by reference. USP <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging- sets clear guidelines for nuclear pharmacies and radiopharmaceuticals. I support the Board's proposed rule to adopt USP 825 standards with no changes or additions.

Thanks,

Nick Bettinger, PharmD

Pharmacy Manager

1603 North C Ave

Sioux Falls, SD 57104

605-332-3703 Office

262-744-2141 Mobile

Windschitl, Beth

From: Windschitl, Beth
Sent: Friday, March 22, 2024 12:19 PM
To: Shanard-Koenders, Kari; Laetsch, Tyler
Subject: Comments for Proposed Rule Hearing
Attachments: Sign Out Sheet for Non-Pharmacy Hours.docx; Supervisor Orientation to Pharmacy.docx

Received in the pharmacy board general email box.

From: Steve Timmerman <stimmerman@brookingshealth.org>
Sent: Friday, March 22, 2024 12:13 PM
To: SD Pharmacy Board <PharmacyBoard@state.sd.us>
Subject: [EXT] Comments for Proposed Rule Hearing

I did a quick brush through of the proposed changes and do not have any specific questions or suggestions for the actual changes. However, I have always found Section 20:51:15:13 to be difficult to manage because it does not address how to handle refrigerated (or possibly frozen) medications.

My comments:

- Section 20:51:15:13. Access to pharmacy – Records
  - This section does not address how the nurse is to handle the identification for a refrigerated (or possibly frozen) medication.
  - The attached documents are what we use for our facility. This is from the document that I use for training the nurse supervisors that have access to Pharmacy:

- Sign Out for Non-Pharmacy hours
  - Fill in blanks
  - Leave an example
    - Box or individual unit
    - If from refrigerator or freezer then no example needed unless box/package for the item can be left on the counter

Many refrigerated medications come with multiple vials in a box so if only one vial is needed then it is not practical to leave a box/package.

I appreciate your consideration to revised language for this section for the reason noted above. Please let me know if you would like any additional information. Thank you.

Steve Timmerman
Director of Pharmacy
stimmerman@brookingshealth.org

Brookings Health System

300 22nd Avenue
Brookings, SD 57006
Phone: (605) 696-8055
Fax: (605) 696-8806

BROOKINGS HOSPITAL PHARMACY   Brookings, South Dakota 57006-2496

RECORD OF REMOVAL OF MEDICATIONS DURING NON-PHARMACY HOURS

Only a single dose of medication may be removed for patient use.   Floor stock medications must be obtained during Pharmacy hours.

**** PLEASE leave an example of the medication signed out (except refrigerated medication). ****

DATE	TIME	PATIENT'S NAME	ROOM NO.	REMOVED BY	NAME OF MEDICATION REMOVED	STRENGTH REMOVED	QUANTITY REMOVED	PHARMACY USE I.D.	PHARMACY USE CHARGED

Supervisor Orientation to Pharmacy

- General Layout
  - Pharmacist and technician work areas
  - Location/storage for patient's own medication (sheet in chart that needs to be signed and dated)
  - Cart fill area
    - Medications being used
    - Drawers have some common injectable medications
    - Cart exchange drawers – can look here for bulk items that may not have been switched
  - Ophthalmics
  - Orals/rectals (internal meds)
    - Unit dose items
    - Bulk and half tablet items
    - Same generic item but different strengths and may be on different shelves
    - Look carefully for similar items (e.g., metoprolol tartrate vs. metoprolol succinate/XL)
  - IV Rooms
  - Refrigerator and Freezer
    - No longer need to check temperatures during the night. The wireless temperature monitoring system is linked to Steve's phone and the nurse supervisor phone.
    - If alerts are received and out of range then contact Steve or the pharmacist on call.
  - IV fluid rack
  - Injectables
  - Bulks/piggybacks/miscellaneous
  - Non-formulary medications
  - Topicals
  - Inhalers/nebs
  - Controlled Substances
    - All in Omnicell Controlled Substance Management (CSM) system
    - Most controlled substances are in cabinets on the units
    - Pharmacist on call will need to come in if the medication is not on the units

- Medication carts – A bulk item (e.g., inhaler, eye drops) may have accidentally been switched into the patient drawer at cart exchange and may have ended up in the drawer that came back to Pharmacy. Before signing out a new item, please look in the patient drawer in Pharmacy if an item is missing from the patient care area.
- Sign Out for Non-Pharmacy hours
  - Fill in blanks
  - Leave an example
    - Box or individual unit
    - If from refrigerator or freezer then no example needed unless box/package for the item can be left on the counter
- Quantity of an item may be more than two to make a dose but if you need to sign out more than two of something to make a dose then it should "raise a flag" and the dose should be verified with a pharmacist.
- Don't guess on anything!! **Please call the pharmacist on call if there are ANY questions.**
  - Steve is on call the majority of the time. His cell is 690-1817.
  - If Steve is out of town then a notice will be sent out to let you know which pharmacist is covering call.

Notes:

This information was reviewed on _____.

New Supervisor: Printed name: _____

Signature: _____

_____

Steve Timmerman, Director of Pharmacy

Lorri Walmsley, RPh., FAzPA
Director, Pharmacy Affairs
Walgreen Co.
5330 E. Washington St, Ste. 105
Phoenix, AZ 85034
p: 602-214-6618
lorri.walmsley@walgreens.com

April 8, 2024

South Dakota State Board of Pharmacy
4001 W. Valhalla Blvd., Suite 106
Sioux Falls, SD 57106
Attention: Kari Shanard-Koenders, R.Ph., M.S.J. Executive Director

Via Email: kari.shanard-koenders@state.sd.us

RE: Proposed Rules

Dear Director Shanard-Koenders,

On behalf of all pharmacies owned and operated by Walgreens licensed in the State of South Dakota, we thank the Board for the opportunity to comment on these proposed regulations.

Walgreens also thanks the Board for updating their rules to clarify and streamline the current regulations. As part of this process, Walgreens asks the board to provide additional clarity to Chapter 20:51:13:02. The return of unused drugs is common practice between commonly owned pharmacies, for instance when a central fill pharmacy receives products from an originating pharmacy when not dispensed to a patient. This practice helps reduce medication waste, overall inventory costs, and most importantly ensures that medications are in the pharmacies where they will be ultimately dispensed and used by the patients who need them. We ask the board to include additional language in this rule to continue to allow the practice of "returning" or transferring drugs between commonly owned pharmacies, so long that the integrity of the product is ensured, and the product has not been dispensed to the patient.

> **20:51:13:02. Return of unused ~~drugs.~~** Pharmacists Except as otherwise provided by chapters 20:51:21 and 20:51:35, pharmacists and pharmacies ~~are prohibited from accepting~~ may not accept from patients or their agents, for reuse, reissue, or resale, any unused drugs, prescribed medications, ~~poisons,~~ sickroom supplies, or hygienic surgical appliances or garments, unless the product was not dispensed to a directly to a patient. ~~However, in~~ In a hospital with a licensed pharmacy, unused drugs, sickroom supplies, hygienic surgical appliances or garments, ~~or~~ and other items dispensed for hospital inpatients may be returned to the pharmacy, for credit and disposition by a pharmacist, if the integrity of the products and packages is maintained.

The use of support personnel in a pharmacy is crucial to ensuring that licensed staff may focus on patient care and prescription processing duties. Walgreens requests the board to consider including inventory management as an allowed duty for support personnel. As a non-discretionary task that requires no specialized clinical or patient care training, inventory management by support personnel will reduce the workload of the licensed team members, allowing them to focus more on patient care activities.

> **20:51:22:05. Support personnel.** Support personnel are those persons other than a licensed pharmacist, a registered pharmacy intern, or a registered pharmacy technician,

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who may perform nontechnical duties assigned by the pharmacist under the pharmacist's supervision, including ~~the~~ delivery, billing, cashier, custodial, maintenance, inventory management and clerical functions. ~~Support personnel are expected to perform their duties outside the dispensing area of the pharmacy.~~

Appropriately trained pharmacy support personnel may perform the following nontechnical functions involving the handling of prescription drugs, which have been delegated to them by the supervising pharmacist:

(1) The duties of a pharmacy clerk, including placing a prescription container into a bag or sack for delivery to the patient as part of the sales transaction after the accuracy of the prescription has been verified by the pharmacist;

(2) Assisting with ordering, processing returns, inventory management functions, opening drug shipments and affixing appropriate inventory or price stickers to drug stock bottles or containers;

In today's healthcare system, there is increasing pressure to deliver high-quality services to more patients. The use of pharmacy technicians to perform additional administrative and non-discretionary tasks is essential to maximizing the time pharmacists are focused on clinical services and direct patient interactions. Appropriately trained and supervised technicians are more than capable of assisting with and completing the transfer of non-controlled prescriptions. 19 states already allow pharmacy technicians to transfer prescription drug orders in a community setting.[1]

20:51:23:01. Transfer of original prescription information permitted. For the purpose of dispensing ~~refills of~~ prescriptions, a pharmacy may transfer prescription information to another pharmacy, subject to the following requirements:

(1) The transfer is limited to the number of refills total quantity authorized on the original prescription;

(2)The transfer is communicated directly between two licensed pharmacists or for non-controlled substances registered interns, or technicians either verbally or by facsimile; and

(3)Both the original and the transferred prescriptions are kept for two years from the date of the last refill.

Additionally, many state boards of pharmacy have relaxed or eliminated restrictive ratios to allow for optimal use of pharmacy technicians. Other groups, including the National Association of Boards of Pharmacy (NABP), share the view that the technician-to-pharmacist ratio limit should be eliminated.[2] Walgreens feels that pharmacists must be allowed to evaluate their practice setting and use their professional judgment to determine the appropriate staffing to meet the needs of their patients and the communities they serve. We request that the board eliminate or expand its current restrictive ratio and ensure alignment with all practice settings in the state of South Dakota. If the PIC of a hospital, mail order facility, or long-term care facility is able to determine the appropriate staffing levels, why would a community pharmacist not also be able to use their professional judgment for their practice setting? Of note, during the height of the pandemic, expanded ratios were approved and utilized in the state of South Dakota for many community pharmacies. And while these expanded ratios were utilized, there were no additional safety concerns. Walgreens requests the board to allow all pharmacists the ability to utilize professional judgment when determining an appropriate number of technicians, they may supervise to provide safe, efficient, and effective patient care in community pharmacy settings.

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20:51:29:19. Ratio. The ratio of pharmacists ~~to~~ pharmacy technicians ~~to pharmacists that~~ who may be on duty in a pharmacy at a given time ~~is one pharmacist to three technicians~~ must not exceed what the pharmacist on duty deems appropriate for public safety ~~for every pharmacist~~. A pharmacy intern does not count in this ratio (in accordance with § 20:51:02:11.01).

Expanded pharmacy technician duties can provide additional capacity for pharmacists to provide direct patient care, supervision of prescription processing and increase the accessibility of services for patients. Individual studies demonstrate that expanded technician duties are safe and effective. In addition to expanded technician ratios, a study conducted with available statewide data from Idaho, compared with its border states, suggests that expanded technician duties, such as receiving new or transferred prescriptions information, did not adversely impact patient safety outcomes or the pharmacist job market.[3] Reducing the non-clinical workload for pharmacists by utilizing appropriately trained technicians is not only a benefit to patient safety and health outcomes. This is especially important as recent research has also demonstrated that patients visit community pharmacies almost twice as often as primary care providers and that community pharmacies are particularly successful at reaching rural residents and patients who otherwise would not be reached by other health care providers.[4,5]

20:51:29:21. Technical functions. At the discretion of the supervising pharmacist, technical functions ~~which~~ that may be delegated to a pharmacy technician include ~~the following~~:

(1) Performing packaging, manipulative, or repetitive tasks relating to the processing of a prescription or medication order in a licensed pharmacy;
(2) Accepting new prescription or refill authorization communicated to a pharmacy by a prescriber, or by the prescriber's agent~~;. Any changes other than the number of refills on the prescription may not be accepted by a technician and must be accepted by a pharmacist or pharmacy intern~~;
(3) Contacting prescribers to obtain prescription refill authorization;
(4) Collecting pertinent patient information;

Walgreens feels that the language in 20:51:36:03 might cause confusion and imply that both the central fill pharmacy and the originating pharmacy must perform a prospective DUR before dispensing the prescription. Amending 20:51:36:03 to confirm that a prospective DUR is complete before dispensing to the patient will prevent confusion and duplicate work at both pharmacies. Additionally, ensuring that the board and both pharmacies have an audit trail of who has performed the DUR and is available upon request will also clarify the language and ensure that both the originating pharmacy and central fill pharmacy comply with the intent of this rule.

Audit trail and that all steps have occurred.

20:51:36:03. Requirements for central fill. The originating pharmacy and central fill pharmacy must:

(1) Be under the same ownership or have a signed legal contract to provide central fill services;
(2) Share a common prescription software platform, as described in § 20:51:20:04;
(3) ~~Have~~ Ensure a pharmacist performs a prospective drug utilization review in accordance with§20:51:25:02 before dispensing any prescription. The identity of the pharmacist must be available for auditing purposes and upon request from the board at ~~to~~ both pharmacies ~~in the prescription record~~; and

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Walgreens would also like to recognize and thank the board for allowing certified technicians to administer vaccines under the supervision of a pharmacist in Chapter 20:51:28:02.02. This change once again shows the Board's commitment to public health and safety. Currently, less than 12 states, including South Dakota and Washington DC remain where permanent authority allowing appropriately trained technicians to administer vaccinations upon the discontinuation of the PREP Act in December 2024. Studies show that pharmacy technicians have safely administered immunizations, especially during the COVID pandemic and hypothetical concerns have not materialized. Additionally, supervising pharmacists have felt comfortable with delegating this task and the number of vaccine-preventable diseases has been reduced because of increased access to vaccines in communities across the Nation.[6]

Walgreens again thanks the Board for the opportunity to comment on these proposed regulations. If the Board would like additional information, please feel free to contact me.

Sincerely,

Lori Walmsley

Lorri Walmsley, RPh, FAzPA

1) The National Association of Boards of Pharmacy Task Force on Pharmacy Manpower Shortage Committee Report for 1999-2000
2) *Survey of pharmacy law*. National Association of Boards of Pharmacy. (2024, February 14). https://nabp.pharmacy/news-resources/resources/publications/survey-of-pharmacy-law/
3) Adams AJ. Extending COVID-19 Pharmacy Technician Duties: Impact on Safety and Pharmacist Jobs. Pharm Technol. 2023 Jun;39(3):134-138. doi: 10.1177/87551225231172343. Epub 2023 May 24. PMID: 37323767; PMCID: PMC10209718.
4) San-Juan-Rodriguez A.Newman T.V.Hernandez I.et al.Impact of community pharmacist-provided preventive services on clinical, utilization, and economic outcomes: an umbrella review.Prev Med. 2018; 115: 145-155
5) Qato DM, Zenk S, Wilder J, Harrington R, Gaskin D, Alexander GC. The availability of pharmacies in the United States: 2007–2015. PLoS One [Internet]. 2017 Aug 1 [cited 2024 Nov 30]. Available from: /pmc/articles/PMC5559230/?report=abstract
6) Adams AJ, Bright D, Adams J. Pharmacy technician-administered immunizations: A five-year review. J Am Pharm Assoc (2003). 2022 Mar-Apr;62(2):419-423. doi: 10.1016/j.japh.2021.11.011. Epub 2021 Nov 14. PMID: 34857489; PMCID: PMC8590632.

Windschitl, Beth

From: Windschitl, Beth
Sent: Tuesday, April 9, 2024 7:51 AM
To: Shanard-Koenders, Kari; Laetsch, Tyler
Subject: FW: [EXT] Proposed edit / Exemption Request

Forwarding , rules comments received in the general email box.

Sincerely,

Beth Windschitl
Senior Secretary
South Dakota Board of Pharmacy
4001 W. Valhalla Blvd, Ste 106
Sioux Falls, SD 57106
beth.windschitl@state.sd.us

From: Ian Alverson <Ian.Alverson@MadisonHospital.com>
Sent: Monday, April 8, 2024 8:48 PM
To: SD Pharmacy Board <PharmacyBoard@state.sd.us>
Cc: Steve Timmerman <stimmerman@brookingshealth.org>
Subject: [EXT] Proposed edit / Exemption Request

SD Board of Pharmacy:

During my last state inspection, Tyler and I discussed the upcoming changes (before the newest 797 was published), and at that time it sounded like going to immediate use for hazardous compounding would not be an issue. When it came time for my latest on site certification for our negative pressure room and C-PEC, I contacted Tony at AT Analytical to discuss what all would be necessary certifications to keep us compliant with USP 800 compounded products for immediate use. At that time he pointed out that he didn't believe there was any immediate use in USP 800. I promptly reached back out to Tyler for clarification and he essentially stated the same thing: as the chapter is written, there is no immediate use for hazardous compounding.

After thoroughly reviewing both the latest version of USP 797 and USP 800, and having several conversations with Tony, Steve Timmerman (Director in Brookings), and other pharmacists from other small facilities within our state I have decided to reach out to the Board to request an exemption either be added to the proposed rules, or for sites that request so in writing. Specifically for 20:51:31:32. I fully understand the intention of USP 800 is to protect all people involved in the handling of hazardous products, throughout the entire chain from possession of the product to the receipt of the final product by the patient. I believe that my plan and request still fulfill that intention, while simply modifying the description of the location with which I would use to compound hazardous products.

The plan I would like to suggest would include following all of the processes laid out in USP 800, without performing the monthly surface sampling of the surfaces within my C-PEC, and not performing the 6 month growth media fill tests required in USP 797 for a segregated compounding area. I would continue to have my negative pressure room (C-SEC) tested every 6 months for the necessary pressure differential and air exchanges. I would also have my C-PEC tested and certified every 6 months for leaks, air exchanges, pressure differentials, etc. This would provide a completely safe

environment for handling hazardous products, but would essentially downgrade to a lesser BUD as used in USP 797 immediate use.

We have an incredibly low volume of hazardous medication preparation at our facility (haven't used our C-PEC in almost 2 years), and the currently proposed rules will greatly increase the cost burden for us to maintain this service. Brookings also has a low volume of hazardous medications and all of the doses they prepare can be done as immediate use. This exemption would meet the intended safety for the compounders and provide a needed service to rural communities. If we are not granted an exemption or there is no modification to the proposed rules, we run the risk of eliminating the ability to offer hazardous compounded products to our patients, and will force them to try and find ways to travel to other communities to receive these lifesaving medications. In discussion with Tony, he stated that so long as our products did not cross state lines, the state should have some ability to allow for slight modifications to federal rules.

Steve Timmerman has reviewed this information and is in support of the above request.

We would be happy to discuss this further, either in person or via follow up email, if you have any questions or need any additional clarification about the request.

Thank you for your consideration.

Ian Alverson, PharmD, BCPS

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