SPEAKER JON HANSEN, CHAIR | PRESIDENT PRO TEMPORE CHRIS KARR, VICE CHAIR
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SOUTH DAKOTA
LEGISLATURE
LEGISLATIVE RESEARCH COUNCIL

July 7, 2025

Mr. Tyler Laetsch
Board of Pharmacy
4001 W Valhalla Blvd, Suite 106
Sioux Falls, SD 57106

Dear Mr. Laetsch:

The Legislative Research Council (LRC) received proposed rules from the Board of Pharmacy on June 23, 2025. In accordance with SDCL 1-26-6.5, the LRC reviewed the proposed rules for form, style, clarity, and legality, and now returns them with recommendations.

Please find enclosed:

- Proposed Rules Review Checklists;
- The proposed rules with recommended form, style, clarity, and minor legality edits;
- Directions for Submitting the Final Draft of the Rules; and
- The Interim Rules Review Committee Rules Presentation Format.

In addition to the recommendations provided in the enclosed packet, LRC identifies the following substantial legality issues:

- **Section 20:51:04:01** (packet pg. 19) describes two fees that an applicant for pharmacist licensure by reciprocity must pay in order to receive licensure. Subdivision (2) describes a $150 fee that appears to comply with SDCL 36-11-19. Subdivision (3) references an "initial pharmacist licensure fee" of $35. There appears to be only a single reference to an initial licensure fee in SDCL chapter 36-11, and it is for telepharmacy, per SDCL 36-11-72. There is a fee authorized in chapter 36-11 with a maximum of $35, but it is the application fee for pharmacist licensure by examination, in SDCL 36-11-16(2). What statutory authority allows for the charging of this "initial pharmacist licensure fee"? If the $35 fee is indeed an application fee, then it would appear to violate SDCL 36-11-19's requirement that a maximum of $150 may be charged to reciprocity applicants for an application fee.
- **Section 20:51:06:02** (packet pg. 27) assesses a $50 fee "for a pharmacist-in-charge change". It appears that SDCL 36-11-37 has been added to ostensibly provide a statutory basis for the fee. That statute, however, pertains to a pharmacy license transfer, and a pharmacist-in-charge change is not a pharmacy license transfer, or it would have been described as such in rule. What statutory authority permits this fee?
- **Section 20:51:06:09** (packet pg. 33) describes the effect on a pharmacy license of a pharmacist ceasing to be in active management of the pharmacy, and how a pharmacy may continue to operate with the death of the pharmacist owner. The latter portion of the last sentence describes a transfer of a pharmacy license to a "nonpharmacist owner". SDCL 36-11-37, however, expressly envisions transfer of ownership to only be to "another pharmacist." With the repeal of SDCL 36-11-40, is there any statutory authority that authorizes transfer of a pharmacy license to a non-pharmacist owner?
- **Section 20:51:06:10** (packet pg. 34) describes the ability of a pharmacy to continue operation in the absence of a licensed pharmacist. And yet, SDCL 36-11-48(2) prohibits a pharmacy from "the transaction of business without a pharmacist in charge thereof." This rule attempts to circumvent the plain statutory prohibition by creating a distinction between a "prescription department" and a "general merchandise area" within the pharmacy, to suggest the latter can be kept open without a pharmacist. Yet both are declared to be a part of a licensed pharmacy

per § 20:51:06:03 (pg. 29). What statutory authority allows for this distinction to be made, notwithstanding SDCL 36-11-48(2)'s plain prohibition? Perhaps it should be made clearer in rule that the "pharmacy" licensed is the prescription department, via revision of § 20:51:06:03?

- **Section 20:51:07:03** (packet pg. 36) requires a pharmacy owner to make available and maintain the minimum equipment needed to provide pharmacy services "as determined by the pharmacist-in-charge." SDCL 36-11-41 requires a pharmacy to be equipped with pharmaceutical instruments and utensils "prescribed by the board in rules promulgated in accordance with chapter 1-26..." The statute envisions that the board list the minimum equipment needed in rule, while the rule itself appears to delegate the authority to prescribe the minimum equipment needed to the pharmacist-in-charge. Thus, this rule appears contrary to statute and should be revised to prescribe the actual minimum equipment needed.
- **Section 20:51:13:05** (packet pgs. 43 and 44) authorizes the use of a remote pick-up site for prescription medications by a pharmacy. No statutory authority was provided for the rule that specifically authorizes the use of a remote pick-up site. SDCL 36-11-15 prohibits any person, other than a pharmacist, from dispensing drugs, and 36-11-44 prohibits the dispensing of prescriptions or the vending of drugs in the pharmacist's place of business except under the personal supervision of a pharmacist. Furthermore, "dispensing" is defined in SDCL 36-11-2 as the "preparation and *delivery of a drug* to a patient or a patient's agent...", and "delivery" is defined as the "actual, constructive, or attempted transfer of a drug...from one person to another..." Thus, further statutory authority should be provided to justify the promulgation of this rule, or the rule should be removed. Note that this same issue was raised in the Board's rules packet submitted last year.
- **Section 20:51:13:06** (packet pg. 45) authorizes a pharmacy to provide "a limited number of prescription medications to a clinic for *dispensing* to a patient when access to a pharmacy is limited." Similar to the concerns noted above, no statutory authority was provided that specifically authorizes this type of dispensing arrangement, while significant statutory authority to the contrary implies that this arrangement is not permitted. Further statutory authority should be provided to justify the promulgation of this rule.
- **Chapter 20:51:33** (packet pgs. 111 to 116) establishes complaint procedures for persons regulated by the Board. This chapter does not appear to account for the uniform complaint process set forth in SDCL chapter 36-1C, which applies to all professional or occupational licensing boards in title 36. The uniform complaint procedure legislation was codified in 2021, and chapter 20:51:33 has not been modified since its inception in 2018. The rules chapter must be revised to reconcile the conflicts and redundancies with the superior authority for complaint procedures in statute, unless it can be shown that SDCL chapter 36-1C is not applicable to pharmacy.

As this rule proposal entails a fee increase, the Board is required to provide the information described in SDCL 1-26-4.8 to the Interim Rules Review Committee. Please complete the Form 17 and provide it to the Committee and LRC with the final packet submission, prior to the Committee meeting date.

Under SDCL 1-26-4(4), the Board is required to adopt LRC recommendations, subject to an appeal to the Interim Rules Review Committee for the Committee's final determination. Note, however, that LRC reserves the right to withdraw recommendations if they are resolved via discussion with Board staff.

Please do not hesitate to contact me if you have any questions or to discuss and possibly resolve any of the recommendations.

Sincerely,

Justin J. Goetz
Code Counsel
Enclosures

CC: Melissa Magstadt, Secretary, Department of Health

Legislative Research Council
Proposed Rules Research Review Checklist

Date Proposed Rules Received by LRC:	June 23, 2025
Date Public Hearing Scheduled:	July 17, 2025
Proposed Rules Reviewed by:	Anna Madsen
Fiscal Note Reviewed by:	Bill Douglas

"No agency rule may be enforced by the courts of this state until it has been adopted in conformance with the procedures set forth in this chapter." (SDCL 1-26-6.8)

Staff:
Please review the proposed rules and supporting documents and submit them with this completed checklist to the Code Counsel within ten business days from the date the proposed rules are received by the LRC.

KEY

ENTRY:	"[Initials]"	"N/A"	"[Initials]*"
MEANING:	Reviewed by	Not applicable	Edit Recommended or Issue

1. Verify the rules packet includes (SDCL 1-26-4(2)):
   a. The proposed rules: AM
      i. Any incorporated material: N/A
   b. Notice of hearing (Form 6): AM

2. Verify all documents have correct citations to the proposed rules provided in the packet. AM

3. Verify the appropriate departmental secretary, bureau commissioner, public utilities commissioner, or constitutional officer approved the rules process to proceed. (SDCL 1-26-4(1)) AM

4. **If the Department of Social Services is promulgating rules that are mandated by federal statute or regulation, use the DSS Federal Regulations Checklist.**

5. Review proposed rules for:

   a. Form, style, and clarity in accordance with the Administrative Rules Drafting Manual (including all existing language, not just amended language). AM*

      i. Verify the most recent rule is used. (Manual, pg. 5) AM

      ii. Verify all cross-references in text are current. (Manual, pg. 6) AM*

      iii. Verify all affected sections are included. For repealed sections, verify all affected sections are amended. (Manual, pg. 6) AM

      iv. Verify any renumbering of rules is consistent with Administrative Rules Drafting Manual. (Manual, pg. 7) AM

b. Legality, including:

i. Verify the General Authority statute provides rule-making authority (i.e., ". . . shall/may promulgate rules to . . ."). (Manual, pg. 8) AM*

ii. Verify the Law Implemented statute identifies the policy intended to be implemented. (Manual, pg. 8) AM*

iii. If the proposed rule incorporates material by reference, verify the rule describes the exact section or portion of the material. (SDCL 1-26-6.6; Manual, pg. 11) AM*

For incorporated material that is not CFR, USC, Fed. Reg., Stat.:

1. Verify the proposed rule includes a reference note identifying the publication by title, date of publication, author, version/edition and where and at what cost the publication may be obtained. AM

2. Verify there is a statement attached to the material that includes the agency's name, the section number of the rule that incorporates the material, and the date the proposed rule was served on the LRC. N/A

iv. Verify the proposed rule does not incorporate or reiterate any statutory language other than definitions, and that the agency is not publishing or distributing statutory material. (SDCL 1-26-6.1) AM*

v. Verify the proposed rule does not restrict any right or privilege to carry or possess a concealed pistol under SDCL chapter 23-7. (SDCL 1-26-6.10) AM

vi. Verify the agency does not delegate authority to a private association. (S.D. Const. art. III, §§ 23(9), 26) AM

vii. Verify the rule does not allow the agency to circumvent the SDCL ch. 1-26 rulemaking process (e.g., authorizing it to make its own rules). (*See* SDCL 1-26-4, 1-26-6.5, 1-26-6.6, 1-26-38(2)) AM

viii. Verify the rule does not contain the agency's internal processes or policy (e.g., personnel policies) or other matter that is not defined as a rule per SDCL 1-26-1(8). AM

ix. Verify the rule does not incorporate a future rule or regulation, or incorporate future amendments to an existing rule or regulation, of another state or the federal government. (*State v. Johnson*, 84 S.D. 556, 173 N.W.2d 894 (1970)) AM

x. Verify only the rules being changed are included in the packet and that chapter indexes are updated as needed. (Manual, pg. 8) AM

6. Review Notice of Public Hearing (SDCL 1-26-4.1):

a. Verify the LRC received the proposed rules at least 20 days prior to the scheduled public hearing. AM

b. Verify the notice contains a narrative description of the effect of the proposed rule. AM

c. Verify the notice contains the reason for adopting the proposed rule. AM

d. Verify the notice contains the location, date, and time (Central or Mountain) of the hearing. AM

e. Verify the notice contains information about how amendments, data, opinions, and arguments may be presented. AM

f. Verify the notice contains a deadline for submission of comments. AM

i. If the authority promulgating the rule is a secretary, commissioner, or officer, ensure the deadline is ten days after the public hearing. (SDCL 1-26-4(6)) N/A

ii. If the authority promulgating the rule is a part-time citizen board, Commission, committee, or task force, ensure the deadline is at least 72 hours before the public hearing (not including hearing day). (SDCL 1-26-4(6)). AM

g. Verify the notice contains information for how the public may obtain copies of the proposed rules. AM

7. For any proposed rule regarding professional or regulatory examination or licensing that is to be published in pamphlet form, review the pamphlet for style, form, and clarity in accordance with the Administrative Rules Drafting Manual. (SDCL 1-26-11) N/A

Reviewed by Code Counsel on _____

Legislative Research Council
Proposed Rules Fiscal Note Review Checklist

Date Proposed Rules Received by LRC: July 17, 2025

Date Public Hearing Scheduled: Anna Madsen

Proposed Rules Reviewed by: Bill Douglas

Fiscal Note Reviewed by: Bill Douglas

"No agency rule may be enforced by the courts of this state until it has been adopted in conformance with the procedures set forth in this chapter." (SDCL 1-26-6.8)

Staff:
Please review the proposed rules and supporting documents and submit them with this completed checklist to the Code Counsel within ten business days from the date the proposed rules are received by the LRC.

KEY

ENTRY:	"[Initials]"	"N/A"	"[Initials]*"
MEANING:	Reviewed by	Not applicable	Edit Recommended or Issue

1. Verify the rules packet includes (SDCL 1-26-4(2)):
   a. Fiscal note (Form 5): AM
   b. Small business impact statement (Form 14): N/A
   c. Housing Cost Impact Statement (Form 16), if applicable: AM
2. Indicate whether the proposed rules:
   a. Increase a fee, in which case, initial. If initialed, the agency must submit a completed Form 17 with the final packet provided to the Interim Rules Review Committee and LRC, pursuant to SDCL 1-26-4(8). (SDCL 1-26-4.8) BD
   b. Increase a fee of a professional or occupational licensing board or commission for which no maximum fee is established in statute, in which case, initial. If the fee increases by more than 20%, note the issue. (SDCL 1-26-6.9) AM
3. Review the Fiscal Note (SDCL 1-26-4.2):
   a. Verify the Fiscal Note states whether the proposed rule will have any effect on the revenues, expenditures, or fiscal liability of the state, agencies, and subdivisions: AM
      i. If there is an effect, verify the Fiscal Note includes an explanation of how the effect was computed? BD
      ii. If there is an effect on subdivisions, is that effect described? BD

4. Review Small Business Impact Statement (SDCL 1-26-2.1):

    a. Verify if the rule change has any small business impact based on readily available info: AM*

        i. If only INDIRECT, verify that a brief description of the impact is included. AM

        ii. If DIRECT, review 4.b through 4.h:

    b. Verify the Impact Statement includes a narrative explanation in plain, easy-to-read language. AM*

    c. Verify the narrative explanation discusses the effect of the proposed rule on small business, including the basis for the rule's enactment and why the rule is needed. AM

    d. Verify the narrative explanation includes an identification and estimated number of small businesses subject to the proposed rule. AM

    e. Verify the Impact Statement includes the projected reporting and record-keeping required for compliance with the proposed rule. AM*

    f. Verify the Impact Statement includes the types of professional skills necessary for preparation of required reports or records. AM*

    g. Verify the Impact Statement includes a statement of the probable effect on impacted small business. N/A

    h. Verify the Impact Statement includes a description of any less intrusive or less costly alternative methods of achieving the proposed rule's purpose. BD

5. Review Housing Cost Impact Statement (SDCL 1-26-2.3), if applicable:

    a. Verify that the agency has indicated what building sectors will be impacted by the rule change. AM*

    b. Verify a description of and explanation of necessity for each each standard and requirement is included. AM

    c. Verify the statement includes the average estimated cost of each standard and requirement. AM

    d. Verify that contact and estimate information is included for three licensed contractors or building trades professionals. AM

Reviewed by Code Counsel on _____

ARTICLE 20:51

PHARMACISTS

Chapter

20:51:23 Transfer of prescription information.

20:51:24 Patient record system.

20:51:25 Patient counseling.

20:51:26 Sterile products for home care patients, Repealed.

20:51:27 Nonresident pharmacy ~~registration~~ licensure.

20:51:28 Administration of immunizations.

20:51:29 Registered pharmacy technicians.

20:51:30 Telepharmacy.

20:51:31 Compounding practices.

20:51:32 Prescription drug monitoring program.

20:51:33 Complaint procedures.

20:51:34 Contested case hearing procedures.

20:51:35 Donated prescription drug and medical supply redispensing program.

20:51:36 Central fill pharmacies.

CHAPTER 20:51:01

~~REGISTRATION~~ LICENSURE BY EXAMINATION

Section

20:51:01:01. Application for ~~registration~~ licensure. An applicant for ~~registration~~ licensure as a pharmacist by examination shall apply to the board and provide all requested information on or with the application.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; 33 SDR 73, effective November 6, 2006; 36 SDR 21, effective August 17, 2009; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL ~~36-11-15,~~ 36-11-16~~, 36-11-18~~.

Cross-Reference: Examination, § 20:51:01:04.

Commented [A1]: Clarity - Technically not have the catchall definition to refer bac chapter 36-11--e.g., "Terms used in this ar same meaning as chapter 36-11." Some of chapters do, though, so I hesitate to change shorthand references to their full version. I way to add the definitional cross reference

Commented [A2]: Clarity - "informatio board"?

Commented [A3]: Legality - The crimi performing pharmacy services without a p does not appear to be applicable to a rule s how an applicant applies for a license.

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20:51:01:02. Experience required. An applicant meeting the requirements of SDCL 36-11-16 for a ~~certificate of registration as a licentiate in~~ license to practice pharmacy and who is examined after December 31, 2009, must have completed a pharmacy practice experience program ~~which~~ that meets or exceeds the ~~minimum~~ pharmacy practice experience requirements ~~of the board as defined~~ set forth in chapter 20:51:02.

Source: SL 1975, ch 16, § 1; 7 SDR 51, effective December 3, 1980; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996; 36 SDR 21, effective August 17, 2009

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-16.

Cross-References:

Goals and objectives of internship, § 20:51:02:01.01.

Required hours, § 20:51:02:13.

Commented [A4]: Clarity - It looks like experience program" and "internship" are specifically chapter 20:51:02. Are those in terms? If so, recommend that a consistent

Commented [A5]: Style/form - "that" is "which" when the following phrase is esse sentence.

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Commented [A6]: Clarity - Experience minimums by default, are they not?

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Commented [A7]: Legality - ARSD 20: catchlined "Internship experiences from ot catchline being used here is for ARSD 20:

20:51:01:03. Application requirements. An applicant for ~~registration~~ licensure by examination shall provide the following to the board with the application:

(1) The application fee of thirty-five dollars;

(2) A photo of the applicant;

(3) ~~A list of the applicant's practical experience;~~

~~(4)~~ A transcript showing graduation from a college of pharmacy approved by the American Council on Pharmaceutical Education;

~~(5)~~(4) A government-issued form of photo identification; and

~~(6)~~(5) A criminal background check.

Source: SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 8 SDR 144, effective May 4, 1982; 11 SDR 120, effective March 11, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 14 SDR 121, effective March 28, 1988; 15 SDR 20, effective August 9, 1988; 18 SDR 95, effective November 25, 1991; 22 SDR 133, effective April 25, 1996; 33 SDR 73, effective November 6, 2006; 36 SDR 21, effective August 17, 2009; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1), ~~36-11-17~~ 36-11-16.

Law Implemented: SDCL 36-11-16, 36-11-16.1, ~~36-11-17~~.

~~Cross-References~~**Cross-Reference:**

Examination, § 20:51:01:04.

~~Approved colleges of pharmacy, § 20:51:01:09.~~

Commented [A8]: Clarity - If this sectio everything that must be submitted to the b application, is there a need for 20:51:01:0 unnecessary.

Commented [A9R8]: Clarity - At the ve reference to "requested information" can li because this rule section describes what th information is in much greater detail. I sup section only implies that an application is license, while 20:51:01:01 makes that an e requirement, but it does make it a close iss 20:51:01:01 has any substantive value.

Commented [A10]: Clarity - How is the completion of the internship requirement t the board, now that this requirement is stru

Commented [A11]: Style - A space alre the ordinal and the first word of the subdiv

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Commented [A12]: Clarity - The backg is not provided by the applicant—the appli fingerprint card/information for the backgr completed. Is this subdivision necessary gi detail in 36-11-16.1?

Commented [A13]: Legality - SDCL 1- agency cite the "subdivision, or subsection provides the Law Implemented. There are subdivisions that may be relevant here—su (5), and (6), perhaps? They should be spec

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Commented [A14]: Style - Changed to note entry. ARSD DM, pg. 20.

20:51:01:04. Examination. An applicant for ~~registration~~ licensure by examination shall successfully complete the North American Pharmacist Licensure Examination ~~(NAPLEX)~~ and the Multistate Jurisprudence Examination ~~(MPJE)~~, South Dakota edition. A total scaled score of not less than ~~75~~ seventy-five is required to pass each examination.

Source: SL 1975, ch 16, § 1; 10 SDR 117, effective May 8, 1984; 12 SDR 178, effective May 11, 1986; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; 33 SDR 73, effective November 6, 2006; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-16~~, 36-11-18~~.

Commented [A15]: Style/form - Abbrev encouraged in the drafting of rules, especia is already used. ARSD DM, pg. 13.

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Commented [A16]: Style/form - Most r out. ARSD DM, pg. 18.

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Commented [A17]: Legality - As noted subdivision should be cited here. It appear (7) is relevant.

20:51:01:10. Application requirements for graduates from colleges of pharmacy located outside the United States. Any applicant who is a graduate of a school or college of pharmacy located outside of the United States must submit the Foreign Pharmacy Graduate Examination Committee ~~(FPGEC)~~ certification awarded by the National Association of Boards of Pharmacy ~~(NABP)~~. The ~~FPGEC~~ Foreign Pharmacy Graduate Examination Committee certification includes the Test of English as a Foreign Language ~~(TOEFL)~~ and the Test of Spoken English ~~(TSE)~~, or the Internet-based ~~TOEFL~~ Test of English as a Foreign Language iBT as a prerequisite to taking the licensure examinations.

~~A foreign pharmacy graduate~~ The applicant shall ~~also be required to~~ obtain internship experience in one or more board-licensed ~~community or hospital~~ pharmacies.

Source: 9 SDR 171, effective July 12, 1983; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; 22 SDR 133, effective April 25, 1996; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-16~~, 36-11-18~~.

Commented [A18]: Clarity - All of the this chapter either use the phrase "applica examination" or refer to an applicant unde Shouldn't this be "Any applicant for licens examination who is…."?

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Commented [A19]: Clarity - Is this sent mean that the individual must take the Eng before taking the FPGEC? Right now, this just as a statement of fact—it doesn't expl applicant to do anything.

Commented [A20R19]: Clarity - If it is of fact, it does not belong in rule. Rule can in the NABP's certification, so it seems lik should be struck if the certification inheren elements already.

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Commented [A22]: Clarity - "as require 20:51:02"? And, is the internship experien practical experience? Without further deta internship experience referenced here is op

Commented [A23R22]: Clarity - More does not expressly refer back to 20:51:01:0 necessary to reconcile these requirements requirements for licensure by examination referencing or some other clarification.

Commented [A24]: Legality - Need to s subdivision here. Perhaps subdivision (6)? subdivision (5), but it does not appear that specifically recognizing colleges outside o it specifies colleges in the U.S. in 20:51:01

20:51:01:11. North American Pharmacist Licensure Examination score transfer. An applicant meeting the requirements of this chapter who has taken the North American Pharmacist Licensure Examination in another state may transfer scores through the National Association of Boards of Pharmacy. To be eligible for licensure, an applicant must ~~complete the requirements of § 20:51:01:03 and~~ receive a passing grade in the Multistate Pharmacy Jurisprudence Examination, South Dakota edition, in accordance with § 20:51:01:04, within one year from the date the scores are transferred by the National Association of Boards of Pharmacy to the board.

Source: 18 SDR 95, effective November 25, 1991; 33 SDR 73, effective November 6, 2006; 36 SDR 21, effective August 17, 2009; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-16~~, 36-11-18~~.

~~**Cross-Reference:** Examination, § 20:51:01:04.~~

~~**20:51:01:12. Registration fee nonrefundable.** Repealed.~~

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Commented [A25]: Clarity - What of th 20:51:01:02? Perhaps retaining the more v requirements of this chapter" in the prior s preferable, and one should strike " comple requirements of § 20:51:01:03 and"?

Commented [A26]: Clarity - Perhaps it specifically citing in rule text § 20:51:01:0 placing that citation in a cross-reference no it is clearer to the reader?

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CHAPTER 20:51:02

INTERNSHIP REQUIREMENTS

Section

20:51:02:01. Definitions. Terms defined in SDCL 36-11-2 have the same meaning in this chapter. As used in this chapter, "pharmacy intern" means:

(1) A person who is registered by the board to engage in the practice of pharmacy while under the supervision of a pharmacist, enrolled in an Accreditation Council for Pharmacy Education (ACPE) accredited school or college of pharmacy, and is progressing toward meeting the requirements for licensure as a pharmacist;

(2) A graduate of an ACPE-approved professional degree program of a school or college of pharmacy, or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate, who is currently registered by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(3) A qualified applicant awaiting examination for pharmacist licensure or meeting board requirements for re-licensing; or

(4) A qualified applicant participating in a pharmacy residency or fellowship program.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996; 31 SDR 35, effective September 19, 2004; 36 SDR 21, effective August 17, 2009; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-16(6), 36-11-25.

~~**Cross-Reference:** Approved colleges of pharmacy, § 20:51:01:09.~~

Commented [A29]: Clarity - The follow
are rather cumbersome. It might be more a
separate out this content as a separate rule
20:51:02:04. Particularly because the subd
requirements of being a pharmacy intern ra
definition, which are intended to be used a
space in the text of a rule. ARSD DM, pg.

Commented [A30]: Clarity - SDCL 36-
pharmacy intern "certificate" rather than re
not see any reference for the registration o
Can that be clarified throughout? Or are th
and registered interns, and they all have ce

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Commented [A31]: Clarity - Same com

Commented [A32R31]: Clarity - "certi
appropriate, but if "registered" is retained,
changed to "currently registered with"?

Commented [A33]: Clarity - Subdivisio
a bit confusing to me and I think further u
these should be reword and reorganized. B
subdivisions above discussed being registe
certificate?) with the board, but these do n
pharmacy intern have to have a certificate
36-11-25?

Commented [A34]: Legality - It seems
the internship is also described in one of th
applying for licensure.

20:51:02:07. Affidavit needed for each practical experience. Any pharmacy intern ~~expecting to receive~~ seeking credit for practical experience as a qualification for ~~registration as a licentiate~~ licensure as a pharmacist pursuant to § 20:51:01:10 shall submit a separate affidavit on a form provided by the board for each practical experience. ~~The affidavit must be submitted to the board before the beginning of the practical experience; however, for good cause shown, the board may accept the affidavit at a later date.~~

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11, 36-11-25.

Law Implemented: SDCL 36-11-16(6), 36-11-25.

Commented [A35]: Clarity - I would su
20:51:02:04 to this packet—as above, the
registration vs. having a certificate should
are also several other rules that could be a
point as well, like 20:51:02:16 (denying re
denying a certificate).

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Commented [A36]: Clarity - is this sub
to be done with the application for licensu
When is this affidavit required to be subm
whom? Again, 20:51:01:03 strikes the req
application to show one's practical experie
requirement in 20:51:01:02 to be proven u

20:51:02:08. Report required at end of each practical experience. ~~At the end of each practical experience, a registered intern shall submit a report to the Board of Pharmacy on a form supplied by the board. The form must be filed within five days after the ending of the experience; however, for good cause shown, the Board of Pharmacy may accept the form at a later date~~ Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996.

~~**General Authority:** SDCL 36-11-11, 36-11-25.~~

~~**Law Implemented:** SDCL 36-11-25.~~

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20:51:02:10. Practical experience defined. The term "practical experience," as it relates to qualification for licensure, means ~~performing~~ the pharmacy intern's practice of pharmacy, as defined in SDCL 36-11-2.2, and the functions authorized to ~~registered~~ pharmacists in SDCL 36-11-19.1, ~~all of which must be performed~~ under the immediate and personal supervision of a ~~registered~~ licensed pharmacist. ~~The Board of Pharmacy may not accept practical experience of more than 48 hours a week or less than eight hours a week.~~

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996.

General Authority: SDCL 36-11-11, 36-11-25.

Law Implemented: SDCL ~~36-11-11~~ 36-11-16(6), 36-11-25.

Commented [A37]: Clarity - Since this could it be moved to the first section of the

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Commented [A38]: Style - Since the ter definition should reflect that.

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Commented [A39]: Clarity - This word since 36-11-2 already defines pharmacist a licensed by the board to engage in pharma

Commented [A40]: Legality - Is there a subdivision that provides Law Implemente Otherwise, this should be struck. Subdivis General Authority, but it does not appear t policy that this rule administers. 36-11-16(appropriate.

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20:51:02:11. Supervising pharmacist requirements. A ~~registered~~ ~~licensed~~ pharmacist who agrees to supervise the practical experience of a registered pharmacy intern shall ~~certify this on a form provided by the board and~~ agree to abide by pharmacy law and rules. A pharmacist must be readily available and in continuous communication with the pharmacy intern during all professional activities of the ~~entire~~ internship. ~~Interns~~ A pharmacy intern may receive written or verbal prescriptions if the pharmacist reviews and makes the necessary professional determinations about the medication order.

A pharmacist shall verify the accuracy of all information entered into the computer by the pharmacy intern. The identity of the pharmacist must be included in the record.

The pharmacist shall inspect the prepared prescription and verify the accuracy of the preparation, and its labeling, prior to dispensing the prescription to the patient or the patient's representative.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996; 26 SDR 92, effective January 6, 2000; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-25.

Commented [A41]: Clarity - Same com

Commented [A42]: Clarity - Since this term, should stay consistent.

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Commented [A43]: Clarity - Here again about practical experience or an internship sentence refers to agreeing to supervise pra

Commented [A44R43]: Clarity - the m makes "entire" redundant.

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Commented [A45]: Clarity - You may w describe here--e.g., "the computer being us

Commented [A46R45]: Clarity - Also, is quite broad. And which computer?

Commented [A47]: Clarity - The record

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20:51:02:12.01. Required hours. An ~~internship must consist of~~ applicant for licensure as a pharmacist pursuant to § 20:51:01:01 must complete a minimum of ~~two thousand~~ one thousand six hundred hours~~, of which one thousand seven hundred forty hours may be a college-based pharmacy practical experience program. The remaining two hundred sixty hours must be acquired under the supervision of one or more preceptors in a board licensed pharmacy where the goal and objectives of a pharmacy internship, as set forth in § 20:51:02:01.01, apply~~ of internship experience.

Source: 36 SDR 21, effective August 17, 2009; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-25.

Commented [A48]: Clarity - Tied into p comments, is internship experience equiva term of "practical experience"?

CHAPTER 20:51:04

~~REGISTRATION~~ LICENSURE BY RECIPROCITY

Section

20:51:04:01. Application. An application to the board ~~shall consist of the official application for license transfer prepared by the National Association of Boards of Pharmacy (NABP) pursuant to the NABP license transfer program~~ for licensure by reciprocity as a pharmacist must include the following:

(1) An ~~Electronic~~ electronic license transfer program official application from the National Association of Boards of Pharmacy, completed on the National Association of Boards of Pharmacy website;

(2) A South Dakota reciprocating pharmacist application, with a non-refundable fee of one hundred fifty dollars;

(3) A non-refundable initial pharmacist licensure fee of thirty-five dollars; and

(4) A criminal background check.

Source: SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 12 SDR 86, effective November 27, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-16, 36-11-16.1, 36-11-19.

Commented [A49]: Style/form - lowerc

Commented [A50]: Clarity - Is there an application? This seems a bit redundant.

Commented [A51]: Clarity - What is th the same as discussed in the first chapter? might be more helpful.

Commented [A52]: Legality - The fee d 36-11-16 that this appears to reference is d "application fee," not an "initial pharmacis The $150 fee referenced in subdivision (2) as an application fee, specific to licensure does not appear that statute envisions the c here, as both are viewed as "application fe latter being specific to licensure by recipro these application fees add up to $185, that violate SDCL 36-11-19.

The term "initial license fee" is only used licensure in SDCL 36-11-72.

Commented [A53]: Clarity - Same as a above, the applicant isn't providing the ba itself.

20:51:04:02. Qualifications for reciprocity. To qualify for a reciprocal ~~registration license in South Dakota~~ license, an applicant must:

(1) Be a ~~registered~~ licensed pharmacist in the state from which the pharmacist is reciprocating;

(2) Be in good standing as a pharmacist in the state from which the pharmacist is reciprocating at the time of application;

(3) Have engaged in the practice of pharmacy for a period of at least one year or have met the pharmacy practice experience requirements of this state within the one-year period immediately prior to the date of application; and

(4) ~~For any applicant who first became a licensed pharmacist after January 1, 1980, the applicant must have~~ Have passed the North American Pharmacist Licensure Examination, if the applicant first became a licensed pharmacist after January 1, 1980.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 36 SDR 21, effective August 17, 2009; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-19.

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Commented [A54]: Clarity - this is a bi
Would "where the pharmacist currently pr
to understand?

Commented [A55]: Clarity - "practical"
the internship vs. practical experience issu

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Commented [A56]: Style/form/clarity -
suggested so this subdivision fits with the

20:51:04:04. Application requirements. ~~An applicant shall complete the official National Association of Boards of Pharmacy (NABP) license transfer application with NABP at NABP.pharmacy. Prior to approval of licensure, the board must receive the following:~~

~~(1) A South Dakota reciprocating pharmacist application with a nonrefundable fee of one hundred fifty dollars;~~

~~(2) A nonrefundable initial pharmacist registration fee of thirty-five dollars; and~~

~~(3) A criminal background check~~ Repealed.

Source: SL 1975, ch 16, § 1; 3 SDR 45, effective December 18, 1976; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 29 SDR 37, effective September 26, 2002; 36 SDR 21, effective August 17, 2009; 50 SDR 138, effective June 2, 2024.

~~**General Authority:** SDCL 36-11-11(1), 36-11-19.~~

~~**Law Implemented:** SDCL 36-11-16.1, 36-11-19.~~

20:51:04:05. Appearance before board. Before issuing a reciprocal ~~registration licensure is granted~~ license, the board may require the applicant ~~may be required~~ to appear in person before the board for final consideration of the reciprocal application. The secretary of the board shall notify the applicant of the time and place of the required appearance.

Source: SL 1975, ch 16, § 1; 10 SDR 117, effective May 8, 1984; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-19.

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20:51:04:08. ~~Certificates of reciprocity~~ Reciprocal license identified by letter R. ~~Certificates of registration~~, ~~Licensure~~, A license granted by reciprocity ~~will~~, must be identified by the letter "R ~~next~~" preceding the license number ~~of such certificates pharmacist license~~.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-5, 36-11-19.

Commented [A57]: Clarity - Suggested consistency. Please update the table of con this change. Changes also suggested below

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Commented [A58]: Legality - SDCL 36 the Board's authority to "hold meetings fo of applicants for licensure and registration

20:51:05:22. Distribution of drugs to prescribers or pharmacies. A ~~registered~~ licensed pharmacy may distribute up to five percent of its controlled drugs and legend drugs to a prescriber licensed to prescribe, dispense, or distribute the drugs in the course of professional practice or to other ~~registered~~ licensed pharmacies, to meet temporary inventory shortages. The distribution must be completed using invoices containing the:

(1) Name, address, and Drug Enforcement Administration number, if required, of both locations involved in the transaction;

(2) Drug name, dosage form, and strength;

(3) Quantity of each drug sold; and

(4) Date of sale.

The sale of Schedule II drugs must include a completed Drug Enforcement Administration form 222. Copies of the invoices must be retained by both locations involved in the transaction for a period of two years from the date of the transaction.

Source: 11 SDR 92, effective January 16, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-14, 36-11A-4.

CHAPTER 20:51:06

PHARMACY PRACTICE AND ~~REGISTRATION~~ LICENSURE

Section

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between the dashes and the preceding and

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20:51:06:01. Application for pharmacy ~~permit~~ license -- Annual renewal required. A ~~registered~~ ~~licensed~~ pharmacist actively conducting a pharmacy in ~~the~~ this state ~~of South Dakota~~ shall apply each year to the board for a ~~permit~~ license to conduct the pharmacy for the year ending June thirtieth on forms provided by the board. The fee is two hundred dollars.

Source: SL 1975, ch 16, § 1; 2 SDR 56, effective February 11, 1976; 4 SDR 85, effective June 19, 1978; 11 SDR 151, effective May 15, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 24 SDR 160, effective May 26, 1998; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3), 36-11-32.

Law Implemented: SDCL 36-11-32, 36-11-35.

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Commented [A60]: Clarity - Can a phar actively conduct a pharmacy, without a lic isn't this section, other than the fee, alread statute, namely 32-11-32 and 32-11-35? It the fee is the only part that needs to be add are two distinct sections authorizing the in for the renewal. E.g., "The fees for a pharm 1)Initial license, two hundred dollars; a 2)License renewal, two hundred dollars

Commented [A61R60]: Style - Make su the subdivisions look like this: (1), (2). Au messes with our recommendations.

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Commented [A62]: Clarity - operate?

Commented [A63R62]: Clarity - SDCL 11-31, 36-11A-9 and 36-11A-11 use "cond manner. "Operate" is used over 2x more in Recommend "operate."

Commented [A64]: Legality - This cont present in SDCL 36-11-35. Does it need to rule?

20:51:06:02. Ownership or control by pharmacist required. ~~A~~ The board may not issue a pharmacy ~~permit license may not be issued~~ license to any ~~pharmacist~~ pharmacy applicant unless the applicant is the owner, or part owner, of the place of business for which a pharmacy ~~registration~~ license is applied for, or unless application is made jointly with a ~~registered~~ licensed pharmacist. If the owner of the place of business for which a pharmacy ~~registration~~ license is applied for is not a pharmacist, the owner must sign an affidavit, on a form prescribed by the board, delegating full and complete authority to the pharmacist-in-charge for active management of the pharmaceutical services in the place of business.

A licensed pharmacy owner may change the pharmacist-in-charge on a form provided by the board at any time during the licensed period. The fee for a pharmacist-in-charge change is fifty dollars. ~~The~~ If the board ~~must be~~ is not notified within ten days of the change, ~~otherwise~~ the pharmacy license becomes void, and the pharmacy owner must reapply for licensure. A complete inventory of controlled substances, as listed in SDCL chapter 34-20B, must be taken on the date of the pharmacist-in-charge change. The inventory ~~shall~~ must be retained in the licensed pharmacy for a period of two years.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3).

Law Implemented: SDCL ~~36-11-32,~~ 36-11-34~~, 36-11-37~~.

Commented [A65]: Style/form - Active preferable. ARSD DM, pg. 14.

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Commented [A66]: Clarity - Presuming back to a pharmacy license, and therefore pharmacy applicant?

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Commented [A67]: Legality - Doesn't t reiterate 36-11-34? If so, it should be struc repeat or reiterate statute. SDCL 1-26-6.1 pg. 5.

Commented [A68R67]: Legality - Agre slight, but substantive, difference in wordi final sentence and subdivision (3) of SDC

Commented [A69]: Legality - Is there a a fee for changing the pharmacy-in-charge authority for a fee when transferring a lice pharmacy, but I understand that the pharm with the owner in this situation. This does transfer as envisioned by statute.

Commented [A70]: Clarity - Perhaps, f "the date that the new pharmacist-in-charg management."

Commented [A71]: Legality - It is uncl application requirements for pharmacist li applicable to a section describing pharmac applications.

Commented [A72]: Legality - As noted a license transfer.

Interestingly, this statute only envisions a transfer being to "another pharmacist." Do non-pharmacist owner under SDCL 36-11 transfer the license?

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20:51:06:02.01. Pharmacist-in-charge ~~-- Defined, duties~~ Definition -- Duties. An application for a ~~permit~~ license to conduct a pharmacy as specified in § 20:51:06:02 must indicate the pharmacist-in-charge. For purposes of this section, the term "pharmacist-in-charge," means a pharmacist manager or pharmacist permittee licensed in this state who has been designated by the pharmacy owner.

The pharmacist-in-charge must:

(1) Be employed or under contract for pharmacy services at the pharmacy;

(2) Establish policy and procedure for the pharmacy;

(3) Supervise all pharmacy employees;

(4) Establish recordkeeping systems for the purchase, safekeeping, storage, compounding, sale, and return of drugs; and

(5) Establish, implement, and document an ongoing quality assurance program in order to maintain and improve facilities, equipment, personnel performance, and the provision of patient care.

The pharmacist-in-charge shall notify the board immediately upon termination of employment. A new pharmacist-in-charge must be designated by the pharmacy owner within ten working days after the termination date.

Source: 26 SDR 92, effective January 6, 2000; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(3).

Law Implemented: SDCL 36-11-32, 36-11-34.

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Commented [A73]: Clarity - Is this for licenses or only when the owner is not a pl could be made more clear.

Commented [A74R73]: Clarity - It reac applies to pharmacy licenses when the own pharmacist. Disregard these comments if t

Commented [A75]: Clarity - Is this still A "permittee" is likely not licensed...

Commented [A76R75]: Legality - In al where this phrase is used in the entire artic being replaced by pharmacist-in-charge or So this term should also be replaced. But w terms replacing this term?

If this term is synonymous with pharmacis this section also apply to pharmacies opera pharmacists per ARSD 20:51:06:01?

Commented [A77]: Clarity - Does the p have to submit the new form envisioned by and be subjected to the fifty dollar fee?

Commented [A78]: Similar to above, do become void if the owner doesn't do this?

Commented [A79R78]: Clarity - And n requirement is "ten days," not "working" d

Commented [A80]: Legality - Perhaps added as well?

20:51:06:03. Application for opening a new pharmacy. An application for ~~an initial~~ a license to operate a new pharmacy ~~permit in license~~ within South Dakota must be filed with the board at least thirty days before the pharmacy's opening date. The board may inspect the pharmacy prior to the opening date.

If the proposed new pharmacy is to include a prescription department, the space ~~registered~~ licensed as a pharmacy must be separated from the remainder of the building in which it is located by walls that extend from the floor to a permanent ceiling. The walls may contain doors to the interior of the building. The doors must be closed and locked whenever a ~~registered~~ licensed pharmacist is not on duty, physically present in the building, and in charge of the pharmacy.

Source: SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3).

Law Implemented: SDCL 36-11-32.

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Commented [A81]: Clarity - The catchl paragraph use "new". Recommend consist a few tweaks suggested to this language.

Commented [A82]: Clarity/Legality - S "the space designated as a prescription dep the language in ARSD 20:51:06:10?

Commented [A83]: Clarity/Legality - S exception described in ARSD 20:51:06:10 and cited here?

Commented [A84]: Legality - Is there a Implemented citations that could be added building requirements of the second paragr refers to the application and fee.

Commented [A85R84]: Legality - Perh is not just about security, but being "free f foreign, or injurious contamination." SDC any event, the telepharmacy rulemaking au clearer about structural and safety compon 11-72(2). Perhaps in a future update of cha could be clarified in statute for all pharmac

20:51:06:04. False application grounds for suspending or revoking. False representation made in an application for a ~~permit to conduct a~~ pharmacy license, or keeping a pharmacy open for the transaction of business without a pharmacist on duty, physically present in the building, and in charge of the pharmacy, except as provided in § 20:51:06:10, are grounds for suspension of revocation of the pharmacy ~~permit~~ license.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3).

Law Implemented: SDCL 36-11-44, 36-11-48.

Commented [A86]: Clarity - There appe grounds than just false information on an a However, isn't this already covered in 36-

Commented [A87R86]: Legality - This because SDCL 36-11-48(2) does not appea exception as provided in 20:51:06:10, unle that the prescription department is what is licensed with a pharmacy license. That, ho appear to be the case, as 20:51:06:03 envis without a prescription department ("If the pharmacy is to include a prescription depa

So what statutory authority provides for th exception is the one unique aspect provide is not contained in SDCL 36-11-48. If that however, this rule literally reads as providi statute, when statute does not appear to all exception to be made. So you are likely be repealing this rule section outright.

Commented [A88]: Clarity - If you reta you could rewrite this into subdivisions fo and ease of adding subdivisions later on. E following are grounds for suspension or re pharmacy license:
1)False representation…"

Commented [A89]: Clarity - "or"?

20:51:06:07. Changes in ownership or location reported to the board--Patients notified of closure of pharmacy. A change in the location, ownership, or name of a pharmacy, or the closure of business as a pharmacy, must be reported to the board at least ten days prior to the change or closure. The ~~pharmacist permittee~~ pharmacist-in-charge is responsible for reporting changes to the board. If a pharmacy permanently closes, patients must be notified thirty days prior to closure.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3).

Law Implemented: SDCL 36-11-37, 36-11-39.

Commented [A90]: Legality - Portions are already covered by 36-11-39. The statu requires notification when the pharmacy m municipality to another. Does that conflict

Commented [A91]: Clarity - notified by

Commented [A92]: Legality - The refer ownership appears to derive from this statu

Where is the statutory authority for change name? If that is not present, shouldn't that removed from rule text?

20:51:06:08. Valid ~~permit~~ license must be displayed. A valid ~~permit~~ license to conduct a pharmacy ~~shall~~ must be displayed in every pharmacy in this state at all times.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-36.

Commented [A93]: Legality - Doesn't t 36-11-36?

Commented [A94R93]: Legality - Agre repeal.

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20:51:06:09. ~~Permit~~ License expires one hundred twenty days after death of pharmacist owner. Except in the event of the death of the ~~pharmacist permittee~~ pharmacist owner, a ~~permit to conduct a~~ pharmacy license is void ~~when~~, if the ~~holder~~ ~~pharmacist owner, of the permit~~ license pharmacist owner ceases to be in active management of the pharmacy. ~~When~~, If a ~~pharmacist permittee~~ pharmacist owner dies, the pharmacy may not be kept open for business without a pharmacist on duty and in charge. A ~~permit to conduct a~~ pharmacy license in the name of a deceased pharmacist becomes void unless transfer of the ~~permit~~ license has been made within the one hundred twenty-day period to a pharmacist owner or to an employee pharmacist manager for whom an affidavit has been filed by a nonpharmacist owner or owners of the pharmacy.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3).

Law Implemented: SDCL 36-11-37, 36-11-38.

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Commented [A95]: Clarity - SDCL 36-
discusses transfer to another pharmacist. Is
have this content in rule, or does statute co

Commented [A96R95]: Legality - Note
Everything after "pharmacist owner" here
transfer of ownership to a non-pharmacist.
only expressly permits ownership transfer
pharmacist. So I don't think this procedure
under statute. If that is the case, then shoul
after "pharmacist owner" be struck?

20:51:06:10. Provisions for pharmacist temporary absence from pharmacy. Where the ~~registered~~ licensed pharmacy includes a prescription department and a general merchandise area, it is not a violation of SDCL chapter 36-11 or § 20:51:06:04 if public entrances to the general merchandise area are kept open for business without a pharmacist on duty in the pharmacy, provided all entrances to the prescription department are closed for the transaction of business and a sign bearing the words "pharmacy services closed" has been posted by the pharmacist before leaving the premises. The prescription department must include sufficient security measures to protect the department from theft or access by unauthorized personnel. The prescription department must be secured by a continuous partition or wall, extending from the floor to the permanent ceiling, with doors capable of being securely locked to isolate the prescription department.

If the prescription department lacks the barrier and is closed, the entire business must be closed, locked, and secured to protect the area from theft or access by unauthorized personnel.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3).

Law Implemented: SDCL ~~36-11-40~~ 36-11-48(2)(6).

Commented [A97]: Clarity - Prior insta "pharmacist on duty" describe a "pharmac charge." Is there a need to get that specific the same as a "pharmacist-in-charge" used throughout these sections?

Commented [A98]: Legality - This sect repealed. What statutory authority permits pharmacy to operate without a pharmacist

SDCL 36-11-40 was an interesting statute. permittee with license owner, and so provi for this concept of transferring ownership pharmacist (and may have been repealed f these concepts).

Now, I think the authority that informs this 36-11-48(2)(6).

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20:51:07:01. Pharmacy must comply with all public health regulations. A pharmacy must comply with all public health regulations regarding sanitation and is subject to board inspections. ~~The pharmacy must be maintained and operated in a clean and sanitary condition, free from unhealthful, foreign, or injurious contamination.~~

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(2).

Law Implemented: SDCL ~~36-11-42~~ 36-11-41, 36-11-64.

Commented [A99]: Clarity - One will n name of the board here, since the definitio chapter 36-11 have not been specifically c chapter of rule, as with other chapters in A

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Commented [A100]: Legality - This co from 36-11-41. Rule cannot repeat statute. and SDCL 1-26-6.1.

20:51:07:03. Minimum equipment requirements. A pharmacy ~~permittee~~ owner must make available and maintain all equipment needed to provide pharmacy services for the location, as determined by the pharmacist-in-charge. Any equipment that requires certification, maintenance, or calibration must be certified, maintained, or calibrated according to the manufacturer and United States Pharmacopeia guidelines. All equipment not in good working condition may not be used in the pharmacy.

Source: SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(4).

Law Implemented: SDCL 36-11-41(1).

Commented [A101]: Clarity/legality - S requires that a pharmacy be equipped with and utensils "prescribed by the board in ru accordance with chapter 1-26…" This sent that authority to the pharmacist-in-charge, conflict with what statute requires.

Commented [A102R101]: Legality - A "equipment chapter," and yet the only rule "equipment" is one that says the pharmaci what equipment is required, and once the p that decision, then the equipment must be way that complies with federal standards.

There were "prescribed" equipment in the revision in 2024. Some kind of requiremen or SDCL 36-11-41(1) needs to be revised.

The determination may/should need to be pharmacist-in-charge, but that determinati based off of "instruments and utensils pres board in rules."

Commented [A103]: Style/form - Com here.

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CHAPTER 20:51:13

SPECIAL RESTRICTIONS

Section

20:51:13:02.01. Return of unused unit dose and unit of issue drugs by patients in hospice programs, nursing facilities, or assisted living facilities. Only unused unit dose or unit of issue drugs from patients in a hospice program, a nursing facility, or an assisted living facility may be returned to the pharmacy that dispensed the drugs for credit and redispensing in accordance with the following requirements:

(1) The facility or hospice program consults with a licensed pharmacist for oversight of the drug distribution to ensure that a person trained and knowledgeable in the storage, use, and administration of the drug has been in control of any drug being returned to the pharmacy and that the unit dose or unit of issue drug has not come into the physical possession of the person for whom it was prescribed;

(2) The ~~pharmacy's manager~~ pharmacist-in-charge has received written approval from the board of a protocol detailing the procedure used to repackage, label, transfer, restock, redispense, and credit any unit dose or unit of issue drugs returned to the pharmacy;

(3) The drugs are provided in the manufacturer's unit dose packaging or are repackaged by the pharmacy in accordance with chapter 20:51:21;

(4) The unit dose package is labeled by the manufacturer with the drug lot number and expiration date;

(5) If the drug is repackaged by the pharmacy, each single unit dose or each unit of issue prepackaged or repackaged container must include:

(a) The name and strength of the medication;

(b) A suitable expiration date, not later than the expiration date on the manufacturer's container or one year from the date the drug is prepackaged or repackaged;

(c) The date the product was prepackaged or repackaged;

(d) The manufacturer's lot number, expiration date, and identity, unless maintained in the internal records of the pharmacy; and

Commented [A104]: Clarity - Since thi long and there is a long list of subdivisions a new sentence here. E.g., "The pharmacy dispense the drugs in accordance with the requirements:"

Commented [A105]: Clarity - "patient"

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(e) The identity of the pharmacist responsible for prepackaging or repackaging, unless maintained in the internal records of the pharmacy;

(6) The drug's packaging is tamper resistant and shows no evidence of contamination~~, such as an opened or stained container~~;

(7) The unit dose drugs have not reached the expiration date;

(8) The drugs have not been dispensed in packaging that intermingles different drugs in a single compartment; and

(9) The drugs are not controlled drugs.

Unused unit dose drugs that are returned under this section may be redispensed pursuant to § 20:51:13:02.03.

Source: 10 SDR 38, effective October 27, 1983; 12 SDR 82, effective November 19, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002; SL 2004, ch 249, § 3, effective July 1, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 34-20H-2, 36-11-46.6.

Cross Reference: Unit dose systems, chapter 20:51:21.

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Commented [A106]: Clarity - Example avoided. ARSD DM, pg. 12.

Commented [A107R106]: Style - If ex particularly necessary, add an Example no this section. ARSD DM, pg. 21.

Commented [A108]: Clarity - Should a of issue be here as well?

Commented [A109]: Clarity - Same? E lead-in of 20:51:13:03.03?

Commented [A110]: Legality - Wouldn be appropriate to use here, too, if one is go subdivisions for General Authority?

20:51:13:02.03. Redispensing unit dose drugs returned from hospice programs, nursing facilities, or assisted living facilities. Unused unit dose or unit of issue drugs that are returned under § 20:51:13:02.01 may be redispensed in accordance with the following requirements:

(1) ~~Drugs that have been repackaged by the pharmacy may be redispensed only one time;~~

~~(2)~~ Drugs in a manufacturer's unit dose package may be redispensed as often as necessary, if the integrity of the original product and package is maintained;

~~(3)~~(2) Drugs that have been repackaged into a unit of issue package by the pharmacy may be redispensed into a unit of issue distribution system and mixed with drugs of a different lot number, provided that all lot numbers and expiration dates are placed on the unit of issue package or in the internal record; and

~~(4)~~(3) Drugs may be removed from a unit dose or unit of issue package, as defined in § 20:51:21:01, for dispensing in a traditional dispensing system ~~as described in § 20:51:21:01~~.

Source: 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 34-20H-2, 36-11-46.6.

Commented [A111]: Clarity - This seer also include unit of issue.

Commented [A112]: Style/form/clarity preferable. E.g., "A pharmacy may only re unused unit dose or unit of issue drug that

Commented [A113]: Clarity - "a traditi system" is not defined in 20:51:21:01, but dose package" and "unit of issue package" the edits to the left, accordingly.

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Commented [A114]: Legality - See abo

20:51:13:02.04. Repackaging drugs from prescription container. Drugs that ~~have been dispensed as a prescription in a traditional dispensing system may not be repackaged into a unit dose or unit of issue package. Drugs~~ were repackaged in a traditional dispensing system ~~that~~ and were not dispensed, or drugs transferred directly from one pharmacy to another pharmacy, may be repackaged into unit dose or unit of issue packaging if the following information is obtained by the ~~receiving~~ pharmacy:

(1) Date received;

(2) Name of drug;

(3) Strength;

(4) Quantity;

(5) Expiration date not to exceed the shorter of one year from the date the drug is prepackaged or repackaged or the manufacturer's container expiration date;

(6) Manufacturer's lot number;

(7) Manufacturer; and

(8) National Drug Code.

Source: 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 34-20H-2, 36-11-46.6.

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Commented [A115]: Clarity - Since thi separate requirement, rather than just infor by the pharmacy as described in the lead-i separate sentence. E.g., "In order to be rep section, the drug's expiration date may not shorter of one year…"

Commented [A116R115]: Clarity - Th recommended above should be placed as a after subdivision (8), in its own paragraph. "separate" is that it is clear to the reader th list of subdivisions.

20:51:13:03. Free choice of pharmacies. The following notice must be displayed conspicuously at all times in all licensed pharmacies:

"NOTICE TO THE PUBLIC

FREE CHOICE OF PHARMACIES

Any person has the right and privilege of having a prescription filled at the pharmacy of the person's choice. This ~~South Dakota~~ State Board of Pharmacy notice must be displayed conspicuously at all times in all licensed pharmacies."

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL ~~36-12B-1~~ 34-12B-1.

Commented [A117]: Clarity - The offic Board, in statute, is "State Board of Pharm 36-11-2(2), 36-11-4.

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Commented [A118]: Style/form - This underlined.

20:51:13:05. Remote pick-up sites ~~-- Approval -- Requirements~~. A licensed pharmacy may designate a ~~location~~ site, other than the pharmacy, where ~~patients~~ a patient may pick up dispensed medications. The pharmacy utilizing the ~~location~~ remote pick-up site retains ownership of the medications received by the patient or designated person and ~~therefore is accountable for~~ shall ensure proper storage and record keeping. To store patient medications ~~awaiting pick-up at a location other than the pharmacy~~ at a remote pick-up site, the pharmacy shall obtain approval from the ~~Board must be obtained~~ State Board of Pharmacy.

~~The following requirements must be met for~~To receive approval, the pharmacy shall submit to the board:

~~(1) A pharmacy must submit the following to the board:~~

(~~a~~1) The name, address, and license number of the pharmacy and name of the pharmacist-in-~~-~~charge responsible for the remote pick-up site;

(~~b~~2) The name and address of each site; and

(~~c~~3) A copy of the policies, procedures, and security requirements for the site.

~~(2) Pick-up site requirements:~~

The following requirements apply to a remote pick-up site:

(~~a~~1) ~~Site~~The site must have a locked cabinet for storage of prescriptions~~:~~

~~(b) Access~~, and access to the locked cabinet ~~should~~ must be limited to trained, designated staff;

(~~c~~2) Prescriptions ~~will~~ must be placed in the locked cabinet immediately upon delivery to the location;

(~~d~~3) ~~Only~~ When storing a prescription bag for pick-up:

(a) ~~the~~The patient's name ~~will~~ must be listed on the outside of the prescription bag~~. The~~, and, if someone other than the patient is picking up the prescription, the designated person's name; and

Commented [A119]: Clarity - Suggest a information here. If you adopt this change, update the table of contents.

Commented [A120]: Clarity - Minor ch for consistency with the catchline.

Commented [A121]: Style/form - Singu preferable. ARSD DM, pg. 15.

Commented [A122]: Clarity - Is there a "medication" is used in certain places vs. " "prescriptions"? Consistent terminology is

Commented [A123]: Clarity - Until the the medication, correct? That should be cla

Commented [A124]: Clarity - This shou referenced in the first sentence for consiste

Commented [A125]: Clarity - Why just Seems like this should be broader--e.g., "E a remote pick-up site, the pharmacy must.

Commented [A126]: Clarity - There is into this list of subdivisions. Recommend requirements for initial approval, which ap subdivision (1), and the rest of the content content, it might be easiest to place the act requirements in a new section following th

Commented [A127]: Clarity - As noted making this a separate section. The follow suggested as if this was a new section.

Commented [A128]: Clarity - Similar t reason this term has switched to prescripti we mean the actual drugs/medications, rig "prescription" is the actual order from the medication/drug itself.

Commented [A129]: Clarity - Uniform here, also. It would appear that "site" is m use here?

(b) The receipt with protected health information ~~will be~~ must be inside of the ~~stapled~~ bag~~. If someone other than the patient will be picking up the prescription, the name will also be listed on the bag~~; and

(c) The bag must be stapled;

(~~e~~4) When the patient or designated person picks up the prescription, ~~The~~ the identity of the patient ~~(~~ or ~~other~~ designated person~~)~~, must be verified. If not personally known by the clerk, the ~~drivers~~ driver license or other photo ID must be checked;

(~~f~~5) The ~~person~~ patient or designated person picking up the prescription ~~will~~ shall sign the receipt or log; ~~and~~

(~~g~~6) A designated employee ~~will~~ shall inventory the prescription bags at least weekly and provide a list of unclaimed bags to the pharmacy; and

(7) A record of all prescriptions delivered to the pick-up site must be maintained in the pharmacy.

~~(3) Pharmacy~~ The pharmacy must maintain a list of all employees at the pick-up site who have been trained and have access to the prescriptions. ~~-~~The pharmacy shall annually review the policies and procedures for the site with each employee and document the date of the review ~~annually;~~

~~(4) A record of shall be maintained in the pharmacy of all prescriptions delivered to the pick-up site; and~~

~~(5)~~. Pharmacy staff ~~must~~ shall conduct and document monthly visits to the pick-up site to ensure compliance with the policies and procedures for the site.

Source:

General Authority: SDCL 36-11-11(1)(3).

Law Implemented: SDCL ~~36-11-2.2(3)~~.

Commented [A130]: Clarity - does the trained and designated? Or who is respons Additionally, active voice is preferable in sentences.

Commented [A131]: Clarity - Often, si refers to a "government-issued" form of id any photo ID suffice here?

Commented [A132]: Clarity - What log

Commented [A133]: Style - "designate above, in the same section. Recommend u

Commented [A134]: Clarity - Recomm following content be a separate paragraph, more to requirements of the pharmacy and

Commented [A135]: Legality - Is there statute that refers to or specifically authori sites? This citation is quite broad. In fact, t instances in statute that seem to conflict w The definition of "dispensing" in 36-11-2 "preparation and delivery of a drug to a pa agent…" and "delivery" is defined as "the constructive, or attempted transfer of a dru person to another…" Does the definition o prohibit this framework, since the drug wo to a patient at a site that is not a licensed p under the direct supervision of a pharmaci

Additionally, SDCL 36-11-44, which proh dispensing or the vending of drugs in the p of business, except under the personal sup pharmacist, and the special statutes on cen pharmacies later in the chapter, also seem point.

Commented [A136R135]: Legality - A the same point I raised last year in the pha submitted then.

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20:51:13:06. Off-site medication~~-~~ control. A licensed pharmacy may provide a limited number of prescription medications to a clinic for dispensing to patients when access to a pharmacy is limited. The pharmacy providing the medications retains ownership of the medications until dispensed to the patient and ~~therefore is accountable for~~ shall ensure proper storage and record keeping. For medications to be stored offsite in a clinic, policies and procedures must be submitted to the State Board of Pharmacy for approval. ~~The following requirements must be addressed in~~ To receive board approval, the policies and procedures must contain:

(1) Location and medication list and quantities;

(2) ~~Medications must~~ A requirement that medications be kept in a locked cabinet with access only by licensed health professionals;

(3) ~~Prior to~~ A requirement that, prior to dispensing ~~the~~ a medication, there must be an order in the patient's record, and a copy of the order or prescription is sent to the pharmacy;

(4) ~~Dispensing~~ A requirement that dispensing at the clinic must be done by the prescriber, or, if the label is prepared by a nurse, the label must otherwise comply with § 20:51:05:21 and the prescriber must verify the drug and the directions prior to dispensing. ~~Labeling must follow ARSD 20:51:05:21~~;

(5) A requirement that a written information sheet ~~should~~ be provided to the patient for each prescription dispensed;

(6) ~~Perpetual~~ A requirement that inventory of all medications stored off-site ~~that includes~~ include a record of each time a ~~mediation~~ medication is dispensed from the supply; and

(7) ~~Pharmacy~~ A requirement that pharmacy staff must conduct an on-site inspection of the medications at least every ninety days which includes inventory of medications, expiration dates, proper storage conditions, and review of procedures with clinic staff.

Source:

General Authority: SDCL 36-11-11(1)(3).

Commented [A137]: Clarity - It seems should mention clinics, since that is a mai rule.

Commented [A138R137]: Clarity - Th catchline provided in the chapter index ab Also, this does not seem to be a proper co Recommend removing the hyphen.

Commented [A139]: Clarity - What do We try to avoid subjective words.

Commented [A140]: Clarity - Note aga terms.

Commented [A141]: Clarity - Is clinic Does this need to be further explained?

Commented [A142]: Clarity - Again, w be limited? Must a pharmacy not be locate distance?

Commented [A143]: Clarity - The phar responsible for proper storage at the clinic not have any accountability in that regard?

Commented [A144]: Clarity - Similar t above, this is broader than just being store

Commented [A145]: Clarity - By who?

Commented [A146]: Clarity - The locat Or location of the medications?

Commented [A147]: Clarity - for the m

Commented [A148]: Clarity - This does lead-in for this section. Is this a requireme the policies and procedures? Or generally labeling must adhere to that chapter?

Commented [A149R148]: Clarity - Se the line above. This is intended to address raised.

Commented [A150]: Clarity - at the cli

Commented [A151]: Clarity - Are these components of the inspection? If it is an ex rephrase to remove "includes". ARSD DM

Commented [A152]: Clarity - just the p policies?

Commented [A153]: Clarity - Is this wi Or just those who are involved with this pr

Law Implemented: SDCL 36-11-2.2(3).

Commented [A154]: Legality - Same le
above.

CHAPTER 20:51:14

GENERAL ADMINISTRATION

Section

20:51:14:01. Annual ~~certificate~~ pharmacist license renewal. The fee for an annual ~~certificate~~ pharmacist license renewal is ~~$125~~ one hundred twenty-five dollars. ~~Certificates~~ Pharmacist licenses expire on September ~~30~~ thirtieth following issuance and must be renewed annually by October ~~1~~ first.

Source: SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 15 SDR 20, effective August 9, 1988; 23 SDR 26, 23 SDR 47, effective August 26, 1996; 28 SDR 24, effective September 2, 2001.

General Authority: SDCL 36-11-23.

Law Implemented: SDCL 36-11-23.

Commented [A155]: Clarity - I wonder could be moved to a chapter that better rel random to have a singular rule related to li far down the article—especially when mos content is in the first few chapters.

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Commented [A156]: Legality/clarity - S expiration date is already specified in 36-1 be struck.

CHAPTER 20:51:15

PHARMACIES IN HOSPITALS, NURSING FACILITIES, OR RELATED FACILITIES

Section

20:51:15:01. Definition and general provisions. Terms used in this chapter mean:

(1) "Chart order," a lawful order entered on the chart or medical record of a patient or resident of a licensed healthcare facility by a practitioner, or a designated agent, for a drug or device;

(2) "Hospice program," a coordinated program of inpatient services providing palliative rather than curative care for a patient;

(3) "Part-time pharmacy," the provision of pharmaceutical services by a ~~registered~~ ~~licensed~~ pharmacist under a pharmacy license issued by the board, on less than a full-time operation basis, in hospitals, nursing facilities, and related facilities in which pharmaceutical services are limited to inpatients; and

(4) "Pharmaceutical services":

(a) The operation, management, or control of a pharmacy;

(b) Preparing, compounding, processing, packaging, labeling, or dispensing one or more doses of medication either upon a prescription or chart order of an authorized practitioner for subsequent administration to, or use by, a patient; and

(c) Any other act, service, operation, or transaction incidental to subsections (4)(a) and (b) requiring, involving, or employing the science or art of any branch of the pharmaceutical profession.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; SL 2004, ch 249, § 2, effective July 1, 2004; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1), 36-11-33.

Law Implemented: SDCL 36-11-33.

Commented [A157]: Clarity - I don't se program" used anywhere in this this chapt

Commented [A158]: Clarity - Could thi "a pharmacy that is licensed pursuant to S is operated on less than a full-time basis"?

Commented [A159R158]: Clarity - it a only used in ARSD 20:51:15:10. Can this removed from this section and added as a ARSD 20:51:15:10? It could begin: "For p section, "part-time pharmacy" means …."

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Commented [A160]: Style - If definitio recommended above, the renumbering wil here, also.

Commented [A161]: Legality - This is General Authority citation.

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20:51:15:02. Pharmaceutical services supervised by pharmacist. All pharmaceutical services ~~shall~~ must be performed either by, or under the personal supervision of, a ~~registered~~ licensed pharmacist.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11, 36-11-33.

Law Implemented: SDCL 36-11-33.

Commented [A162]: Clarity - Performe time pharmacies? This should be clarified.

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20:51:15:03. Central area to be licensed as a pharmacy. The central area in a hospital, nursing facility, ~~and~~ or related ~~facilities~~ facility, where drugs are procured, stored, and issued, and where pharmaceutical services are performed, must be licensed as a pharmacy. The pharmacy ~~must~~ shall meet all requirements of South Dakota and federal law and the rules of the board and ~~must~~ shall have a ~~registered~~ licensed pharmacist in charge ~~of the pharmacy~~.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(3), 36-11-33.

Law Implemented: SDCL 36-11-33.

Commented [A163]: Clarity - Is this no the definition of "pharmaceutical services"

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Commented [A164]: Clarity - "part-tim

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Commented [A165]: Style - The pharm described in this section as an animate sub "must" is not appropriate to use. ARSD D

Commented [A166]: Clarity - Would th other statutes and/or rules?

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20:51:15:04. Dispensing limited to pharmacist. The act of dispensing is limited to a ~~registered~~ licensed pharmacist and may not be performed by any other person except under the personal supervision of a ~~registered~~ licensed pharmacist.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-33.

Commented [A167]: Clarity - Again, in
Perhaps, "Only a licensed pharmacist or a
the personal supervision of the pharmacist
drugs in a part-time pharmacy."

20:51:15:05. Transferring drugs from original containers limited to pharmacists. The act of transferring a drug or preparation from an original container to a new container is an act of dispensing which is restricted to a ~~registered~~ licensed pharmacist.

Commented [A168]: Clarity - Similar t
part-time pharmacy? "Only a licensed pha
transfer a drug or preparation from an orig
a part-time pharmacy."

For purposes of this section, a container is "original" if it has been packaged by a licensed manufacturer and is labeled in compliance with federal and state law.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-33.

20:51:15:07. Preparing a solution. ~~The preparation, by a nurse licensed pursuant to SDCL chapter 36-9, of a solution for injection, is considered a step in the administration of medication~~ Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

~~**General Authority:** SDCL 36-11-11(1).~~

~~**Law Implemented:** SDCL 36-11-2.2.~~

20:51:15:10. ~~Registration and renewal~~Part-time pharmacy license -- Expiration date -- Fee. ~~The board may issue to a pharmacist in good standing a permit license to operate a part-time pharmacy in a hospital, nursing facility, or related facility for the year ending.~~ A license issued by the board to operate a part-time pharmacy expires on June thirtieth~~, if the pharmacist owner applies yearly on a form supplied by the board and pays a~~. The fee ~~of~~ to apply for a part-time pharmacy license is one hundred sixty dollars.

Source: SL 1975, ch 16, § 1; 2 SDR 56, effective February 11, 1976; 4 SDR 85, effective June 19, 1978; 11 SDR 151, effective May 15, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 24 SDR 160, effective May 26, 1998; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3)~~, 36-11-32~~, 36-11-33.

Law Implemented: SDCL~~, 36-11-32,~~ 36-11-33.

Commented [A169]: Legality - Most of already set forth in 36-11-33. I kept the lic in, but would that and the renewal process covered by 36-11-35? If so, only the fee fo is needed here.

Commented [A170R169]: Clarity - The proposed should be adjusted accordingly. pharmacy license -- Fee.

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Commented [A171]: Legality - This sec to the full-time pharmacy licenses.

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20:51:15:11. Schedule of attendance by pharmacist. A ~~registered~~ licensed pharmacist employed or otherwise engaged to supply pharmaceutical services may have a flexible schedule of attendance, but the pharmacist must be present for a sufficient number of hours weekly to ~~maintain~~:

(1) Maintain an adequate supply of medications at the ~~several~~ service areas from which medications are administered~~, to maintain~~;

(2) Maintain all required records~~, to perform~~;

(3) Perform other services permitted or required by law~~.~~; and ~~to provide~~

(4) Provide adequate control over all pharmaceutical services rendered by the hospital, nursing facility, or related ~~facilities~~ facility.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11, 36-11-33.

Law Implemented: SDCL 36-11-33.

Commented [A172]: Clarity - "at a part

Commented [A173]: Clarity - Suggest s for easier readability.

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20:51:15:13. Access to pharmacy -- Records. Only a ~~registered~~ licensed pharmacist may have access to the part-time pharmacy ~~stock of drugs, in the hospital, nursing facility, or related facilities~~. If the pharmacist is absent from the hospital, ~~or other like~~, nursing facility, or other related facility, a registered nurse designated by the hospital may obtain, from ~~a hospital~~ the pharmacy ~~stock of drugs, a unit dose of~~, a drug, or medication necessary to administer to a patient in carrying out treatment and medication orders as prescribed by a licensed prescriber when the drug is not available in floor supplies, or the emergency drug kit, to meet the immediate need of the patient. The nurse shall leave in the pharmacy, on a suitable form, a record of any drugs removed, showing the name of the patient, the name of the drug, the dosage form and strength, the amount taken, and the date and time the drugs were removed, and shall sign the record. The nurse shall leave the record and the container from which the dose was taken, in order that it may be properly checked by the pharmacist. These records must be kept for two years.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(4), 36-11-33.

Law Implemented: SDCL 36-11-2.2, 36-11-33, 36-11-34, 36-11-68.

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Commented [A174]: Clarity - Isn't all c captured by the phrase "part-time pharmac the next few sentences provide an exceptio restriction? If so, then the sentence should provided below, only a licensed pharmacis access…"

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Commented [A175]: Clarity - "nursing related facility"?

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Commented [A176]: Clarity - by who?

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20:51:15:14. Pharmacy must be in a separate room. The pharmacy must be in a separate room and locked at all times when ~~the registered~~ a licensed pharmacist is not on duty.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11, 36-11-33.

Law Implemented: SDCL 36-11-33.

Commented [A177]: Clarity - "part-tim

Commented [A178]: Clarity - "within t nursing facility, or other related facility"?

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20:51:15:15. Pharmacist controls emergency drugs in health care facilities. A pharmacist of a ~~registered~~ licensed pharmacy in a health care facility may provide, upon written request of the health care facility's prescribers, a defined supply of ~~legend~~ drugs in an emergency drug kit or crash cart. The emergency drugs must meet the immediate therapeutic needs of a patient to prevent harm to the patient due to a delay in obtaining ~~such~~ the drugs from the pharmacy. The emergency drugs must remain the property of the ~~registered~~ licensed pharmacy and must be stored on-site in a suitable, controlled location in the health care facility. ~~The emergency drug supplies are governed by the following requirements:~~

~~(1) The facility's registered pharmacist controls the emergency drugs contained in an emergency kit or crash cart;~~

~~(2) Drug quantities are limited, properly labeled, and supplied in single dose packaging, if possible;~~

~~(3) All legend drugs used for an emergency must be identified for replacement by a pharmacist; and~~

~~(4) The pharmacy staff shall restock the contents of the emergency drug supply after each reported use or at least monthly.~~ The pharmacy staff shall inspect all emergency drugs at least monthly.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 26 SDR 92, effective January 6, 2000; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(4), 36-11-33.

Law Implemented: SDCL 36-11-2.2, 36-11-33, 36-11-34.

Commented [A179]: Clarity - "part-tim

Commented [A180]: Clarity - Since nu addressed separately below, should this re consistency with language used previously

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Commented [A181]: Clarity - "part-tim

Commented [A182]: Clarity - Does this just a pharmacist?

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20:51:15:15.01. Pharmacist controls emergency kit in nursing facility. A ~~registered pharmacist~~ licensed pharmacy may provide to a nursing facility a limited quantity of controlled legend drugs ~~pursuant to §§ 44:58:07:09 and 44:73:08:11~~, a limited amount of noncontrolled legend drugs, and nonprescription drugs, for emergency and supportive treatment, if requested in writing by the medical director. The pharmacist shall retain control of all medications provided in emergency kits.

The provider pharmacist shall comply with the following requirements:

(1) The medical director, director of nursing, and provider pharmacist shall jointly determine and prepare a limited list of emergency drugs by identity and quantity. No more than ten different controlled drugs ~~are~~ may be stored in the emergency box, which may not contain ~~no~~ more than twenty doses of any controlled drug;

(2) The provider pharmacy must be notified of any drug taken from the emergency kit;

(3) The provider pharmacy staff shall inventory and restock the contents of the emergency kit after reported use or at least monthly;

(4) The emergency kit must be stored in a suitable, controlled location in the nursing facility to prevent the unauthorized access of the drugs within it. The emergency kit exterior must be labeled clearly~~,~~ that it is an emergency kit and is for emergency use only. The emergency kit must contain the name, strength, quantity, and expiration date of drugs contained therein;

(5) The provider pharmacy may utilize an automated medication distribution device to store, distribute, and record transactions as an emergency kit or for first dose medications~~. If the pharmacy uses an automated medication distribution device, the pharmacy must apply for a separate pharmacy permit to do so unless there is a permitted pharmacy within that physical location~~; and

(6) The provider pharmacy must provide each facility where an emergency kit is placed with a contact number to a pharmacist twenty-four hours a day.

Commented [A183]: Clarity - Is this an the part-time pharmacy affiliated with the

Commented [A184]: Clarity - Since the changing pharmacist to pharmacy, should explained? Or updated to "provider pharm

Commented [A185]: Clarity - What is t box? That hasn't been described thus far. I and below.

Commented [A186]: Clarity - Suggest separate subdivision.

Commented [A187]: Clarity - This subc fit the lead-in. How could the pharmacist c someone else notifies them?

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Commented [A188]: Clarity - again, do lead-in. This is permissive authority, not a

All other controlled and noncontrolled legend medications must be obtained from a pharmacy licensed to ~~distribute~~ dispense to patients pursuant to SDCL 34-12B-1 and 34-12B-2.

Source: 26 SDR 92, effective January 6, 2000; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(4).

Law Implemented: SDCL 36-11-2.2, 36-11-33, 36-11-34.

Commented [A189]: Legality - Neither set forth a specific licensure category. Wh reference trying to get at? That they must the patient's pharmacy of choice, unless th has an exclusive agreement?

20:51:19:03. Hours required. To qualify for a ~~certificate of registration~~ renewal of a pharmacist license or reinstatement, a pharmacist must ~~successfully~~ complete twelve hours of approved continuing education. The twelve hours of approved continuing education required each year for renewal must be completed within the twenty-four months before the pharmacist's ~~certificate of registration~~ license expires. If a pharmacist applies for yearly renewal of the pharmacist's ~~certificate of registration~~ license pursuant to SDCL 36-11-23, in order to receive renewal, the pharmacist must have completed the required hours. If the pharmacist has a certification to administer immunizations, the pharmacist must complete one hour of continuing education related to immunizations, which may be one of the required twelve hours.

For the purposes of this section:

(1) "Approved continuing education," means ~~those~~ continuing pharmaceutical ~~educations~~ education programs made available by an approved provider~~.~~; and

(2) "Approved provider," means any association, corporation, educational institution, organization, or person who has been accredited by the Accreditation Council on Pharmaceutical Education as having met its criteria, indicating the ability to provide quality continuing pharmaceutical education programs, or any sponsor approved by the board in § 20:51:19:09.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 16 SDR 98, effective December 3, 1989; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1), 36-11-23.2.

Law Implemented: SDCL 36-11-23.1 to ~~36-11-23.3~~ 36-11-23.4, inclusive.

Commented [A190]: Clarity - Unneces
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Commented [A191]: Clarity - I am a bi A pharmacist must renew annually. But th continuing education from a different licer Could someone complete 24 hours of cont year, and none in the second? But still cou hours towards their second renewal period
Commented [A192]: Clarity - Hasn't th established above?
Commented [A193R192]: Clarity - Ad "if" suggests it is up to a pharmacist's disc is only up to their discretion if the pharma to practice pharmacy anymore.
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Commented [A194]: Style - Appears to
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Commented [A195]: Clarity - Isn't this be accredited?
Commented [A196]: Clarity - This cros a definition. There are no organizations ac that section. Do you mean 20:51:19:10? N definition of approved provider and that se conflict. What is the difference between ar provider here and a sponsor as used in late an accredited organization still have to go approval process? 20:51:19:10 says that ea must be approved by the board. That shoul reconciled.
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Commented [A197]: Legality - One mo added to this range, as it refers to the Boar establish and accredit programs of continu
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20:51:19:05.01. Audit to verify hours earned. The board shall audit at least five percent of ~~the registered~~ licensed pharmacists at random annually after licensure to verify their continuing education.

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Source: 9 SDR 171, effective July 12, 1983; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-23.2.

Law Implemented: SDCL 36-11-23.2, 36-11-23.3.

20:51:19:14. Attendance by board or council members. Any member or staff of the ~~South Dakota~~ State Board of Pharmacy or advisory council on continuing education ~~shall have the right to~~ established in SDCL 36-11-23.4 may attend and supervise any continuing education program.

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

General Authority: SDCL ~~36-11-10,~~ 36-11-11, 36-11-23.2.

Law Implemented: SDCL 36-11-23.2, 36-11-23.4.

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Commented [A198]: Clarity - "approve

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20:51:25:05. Alternative forms of patient information. Alternative forms of patient information ~~include~~ are written information leaflets, pictogram labels, video programs, or information generated by electronic data processing equipment. ~~When used to replace oral counseling, alternative~~ Alternative forms of patient information ~~shall~~ must advise the patient or caregiver that the pharmacist may be contacted for consultation in person at the pharmacy, or by ~~toll free~~ telephone~~, or by collect telephone call~~. Alternative forms of patient information may also be used to supplement patient counseling.

Source: 19 SDR 93, effective December 31, 1992.

General Authority: SDCL 36-11-68.

Law Implemented: SDCL 36-11-68.

Commented [A199]: Legality - Just a n while going through the current rules—AR has an obsolete Law Implemented citation renumbering of subdivisions from the phar (SDCL 36-11-2(19) should be 36-11-2(15) to update that as well given the clean-up h throughout this packet.

Commented [A200]: Clarity - Suggestio exhaustive.

Commented [A201R200]: Clarity - Mo relevance of the concept of "alternative for information" is not provided in this section back to the section to which it is relevant:

"Alternative forms of patient information, 20:51:25:04, are…"

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Commented [A202]: Clarity - ARSD 20 indicates that alternative forms of patient i be employed when counseling cannot be c telephone. It is not described as an alternat counselling.

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Commented [A203]: Clarity - In an ide would be in first person. "A pharmacist ma forms of patient information…"

20:51:27:02. Application form. The application form for licensure of a nonresident pharmacy must include the information required by SDCL 36-11-19.3 and:

(1) Evidence of licensure in good standing in the nonresident pharmacy's home state;

(2) A description of any disciplinary action against the nonresident pharmacy or the nonresident pharmacy owner, in the home state or any other state within the last four years and the reason for the action;

(3) If the pharmacist-in-charge is not the sole owner or part owner of the merchandise and fixtures of the nonresident pharmacy, an affidavit as described in SDCL 36-11-34;

(4) A list of all other states in which the pharmacy is licensed; ~~and~~

(5) A description of pharmacy services provided to patients located in South Dakota; and

(6) An inspection performed by the regulatory or licensing agency of the home state, any accreditation agency recognized by the board, or the United States Food and Drug Administration, that has been conducted on-site at the ~~licensed~~ nonresident pharmacy within the last four years. ~~Any~~, and any deficiencies on the inspection that require corrective action ~~must be provided with the application~~.

Source: 24 SDR 40, effective October 5, 1997; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3).

Law Implemented: SDCL 36-11-19.3.

Commented [A204]: Clarity - Each of t subdivisions provide "information" - this c "inspection." Do you want the inspection r obviate the need for referencing deficienci language.

Commented [A205]: Legality - SDCL 3 specifically requires the nonresident pharm copy of the most recent inspection report f regulatory or licensing agency of the state located." Is this subdivision meant to requ inspection on top of the one already requir 11-19.3? If not, this rule appears to directl statute.

Commented [A206]: Clarity - Changes the lead-in of the section.

20:51:27:04. Report of change in ownership or location. The owner of a nonresident pharmacy or persons delegated by the owner shall report the following to the board:

(1) Change in pharmacist-in-charge, notify within ten days of change in position status;

(2) Ownership change, notify within thirty days ~~of~~ after the transaction. The license of a nonresident pharmacy is not transferable to a new owner. Any new majority owner of a nonresident pharmacy must apply for licensure pursuant to § 20:51:27:02;

(3) Change in location, notify within thirty days after the transaction. If the location change is to a different state, a new application is required pursuant to § 20:51:27:02; and

(4) Closure of a nonresident pharmacy, notify at least ten days prior to closure.

Source: 24 SDR 40, effective October 5, 1997; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3).

Law Implemented: SDCL 36-11-19.3, 36-11-37.

Commented [A207]: Legality - With th 36-11-40, is there any statutory authority t notice?

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Commented [A208]: Clarity - This cont lead-in. It should be separated out from the

Commented [A209]: Legality - All of t subdivisions have statutory authority that s to reapply for licensure for these reasons w particular timeframes. This subdivision do have such authority behind it, however. If statutory authority requiring the license ap change in location of a nonresident pharma be struck?

Commented [A210]: Clarity - Same as

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~~ by the board;

(2) Has successfully completed an ~~approved~~ immunization training program approved by the board for technicians;

(3) Is certified in cardiopulmonary resuscitation; ~~and~~

(4) Is directly supervised by an on-site pharmacist who has a current authorization to administer immunizations in this state; and

(5) ~~Has completed~~ Completes one hour of continuing education related to immunizations annually.

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

Source: 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(13), 36-11-19.1~~(1)~~.

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-19.1(1).

Commented [A211]: Clarity - Where do come from? The definition of "registered p technician" in 36-11-2 only references bei the board. Certified by who? (see commen into this issue in more detail)

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Commented [A212]: Legality - The rul is specific to "standards for drug administr specific authorization is in the final senten 11-19.1, which is outside of the list of sub

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20:51:29:00. Definitions. Terms used in SDCL 36-11-2 have the same meaning when used in this chapter ~~mean:~~

~~(1) "Certified technician," an individual described in SDCL subdivision 36-11-2(26) 36-11-2(22) who has gained certification through training and examination pursuant to § 20:51:29:06; and~~

~~(2) "Grandfathered technician," an individual not requiring certification, who worked as a technician prior to July 1, 2014, and who has been continuously employed by a pharmacy since that time;~~

~~(3) "Pharmacist~~. As used in this chapter, "pharmacy intern" has the definition set forth in § 20:51:02:01~~; and;~~

~~(4) "Technician-in-training," an individual who is registered with the board to receive on-the-job training in a licensed pharmacy in preparation for certification as a pharmacy technician. A technician-in-training must become a certified technician within two years of registration with the board~~.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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Commented [A213]: Clarity - Why con between registered pharmacy technicians a pharmacy technicians? Only a "registered technician" is used and defined in SDCL c Moreover, national certification is being re requirement. See the comments below re: t adopt those changes, this term wouldn't be chapter. Suggest incorporating the statutor the chapter (if you don't end up doing it fo article), which would include the definitio pharmacy technician."

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Commented [A214]: Clarity - Note the mentioned issue regarding this definition b

20:51:29:01. Purpose of registration. A registration program for all pharmacy technicians is established for the primary purpose of assuring the competency of registered pharmacy technicians and for purposes of identifying, tracking, and bringing disciplinary actions against pharmacy technicians.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

Commented [A215]: Clarity/legality - W have rules that set forth a "purpose" as it d require, prohibit, or authorize an action. Is necessary?

20:51:29:02. Registration required. Any person employed in ~~South Dakota~~ this state as a pharmacy technician ~~or pharmacy technician in training~~ shall obtain and maintain during the employment a current registration as a pharmacy technician ~~or pharmacy technician in training~~ pursuant to this chapter. Any person accepting employment as a pharmacy technician ~~or pharmacy technician in training~~ in ~~South Dakota~~ this state who fails to register as a pharmacy technician ~~or pharmacy technician in training~~ as required by rule may be subject to disciplinary action in accordance with § 20:51:29:27. ~~Prior to renewal of registration 6 hours of continuing education must be completed. The continuing education required to maintain national certification meets this requirement.~~

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

Commented [A216]: Clarity - "individu whenever a natural person is being referen appears to be referenced here.

This revision may need to be made for ma sections for this chapter listed in this pack

Commented [A217]: Style - ARSD DM

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Commented [A218]: Clarity - This sent placed with other renewal requirements. It sense to put in this section. Please see reco below.

Commented [A219]: Legality - I know used throughout this chapter, but it is incre essentially being the sole Law Implemente pharmacy techs. You may want to conside robust statutory framework to support thes

Commented [A220R219]: Legality - A recommended this last year. This did not bill" brought last session, I guess.

20:51:29:03. Original application. ~~Any~~ A person ~~initially applying~~ must submit an initial application for ~~a certificate of~~ registration as a pharmacy technician ~~or pharmacy technician-in-training shall submit an application~~ to the board within thirty days of accepting employment in a South Dakota pharmacy as a pharmacy technician ~~or pharmacy technician-in-training~~.

The board may issue an initial pharmacy technician registration ~~or pharmacy technician-in-training registration~~ to any individual who is ~~sixteen:~~

(1) Sixteen years of age or older~~.~~; and ~~is employed~~

(2) Employed by a pharmacy or ~~is~~ enrolled in a pharmacy technician job exploration program through the high school ~~they are~~ the individual is attending. ~~An individual who was registered by the board prior to July 1, 2011, may renew the individual's registration provided all other requirements for renewal are met and the individual maintains a pharmacy technician registration or national certification on an uninterrupted basis. An individual whose registration or national certification lapses for a period of one year must meet the registration requirements in effect at the time the individual applies for reinstatement of registration.~~

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

Commented [A221]: Clarity - "Initial a registration." ?

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Commented [A222]: Clarity - Suggest a away from mixing certificate/certification/ registration. It's so much clearer just to pic term throughout.

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Commented [A223]: Clarity - What is a pharmacy"? Per licensing, there are nonres telepharmacies, institutional pharmacies, a

Registration is required if the pharmacy te pharmacy tech in South Dakota, per 20:51 have the requirement reflect that rule secti

Commented [A224]: Clarity - Above "p Consistency is recommended.

Commented [A225R224]: Clarity - Sec

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20:51:29:04. College or vocational based training program. A person who is enrolled in a college- or vocational-based pharmacy technician training program shall obtain a pharmacy ~~technician-in-training~~ technician registration from the board prior to beginning any on-site practical experience. ~~The technician-in-training program may not exceed two years' duration.~~

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

Commented [A226]: Clarity - Ideally, t should reflect the dashes as used below.

Commented [A227R226]: Style - Any be made to the chapter index, which will n above. ARSD DM, pg. 6.

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20:51:29:05. Exemptions from registration. A registered pharmacy intern whose South Dakota registration is in good standing and who ~~assists in the technician function of the practice of pharmacy~~ performs any function described in § 20:51:29:21 is not required to register as a pharmacy technician with the board.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(13), 36-11-25.

Law Implemented: SDCL 36-11-2~~(26)~~(22),36-11-25.

Commented [A228]: Clarity - SDCL 36 pharmacy intern "certificate", not registrat rephrasing to "An individual who has a ph certificate issued by the board and who ass technician function…"

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Commented [A229]: Clarity - Why not functions authorized to technicians in rule is the "technician function"?

An intern "is gaining experience as a quali licensure as a pharmacist" per SDCL 36-1 experience described in that statute entirel of the "technician function of the practice ARSD 20:51:29:21? Compare with ARSD In other words, why have pharmacy intern treats them as pharmacy technicians? Or, a specify the functions permitted to pharmac same clear manner as they are provided fo

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20:51:29:06. Certification of pharmacy technicians. A pharmacy technician ~~shall~~ may obtain national certification ~~within two years of registration with the board~~. ~~The board may not renew the registration of a pharmacy technician who was initially registered after July 1, 2011, unless the pharmacy technician is nationally certified~~. To obtain registration as a certified technician, the person must be certified by a national organization and ~~has~~ have passed a pharmacy technician certification examination that is accredited by the National Commission for Certifying Agencies ~~or is in the two-year technician-in-training period~~.

Pharmacy technician national certification does not supplant the need for a licensed pharmacist to exercise control over the performance of a delegated function nor does national certification exempt the pharmacy technician from registration pursuant to this chapter.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

Commented [A230]: Clarity - If this is actual function does obtaining national cer seems like this entire section could be rem national certification is no longer a require me that the only difference is that a tech c certification instead of doing the six contin hours. Please see the recommended edits i that would be based on this section being r

Commented [A231]: Clarity - This und above—why would someone need to be re certified technician? It doesn't appear to a additional tasks or otherwise. Is this regist same as the normal registration process? T clarified. Or is the intent that if you are nat could replace/fast track the regular registra the latter, this needs to be reworded.

Commented [A232]: Clarity - This phra comments above.

20:51:29:07. Registration application form--Fee. The application form for registration as a pharmacy technician must contain:

(1) The applicant's name, address, phone number, date of birth, gender, social security number, and email address;

(2) The applicant's work experience;

(3) Current and past places of employment; ~~and~~

(4) A non-refundable fee; and

(5) Proof of six hours of continuing education obtained within the last twenty-four months or proof of current pharmacy technician certification.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-11(13).

Commented [A233]: Clarity - This sect
apply to the initial application for registrat
odd for continuing education to be require
application. Recommend that this be move
addresses registration renewals, like 20:51
edits recommended below.

20:51:29:08. Declaration of current impairment or limitations. The applicant shall declare any current use of drugs, alcohol, or other chemical substances that in any way impairs or limits the applicant's ability to perform the duties of a pharmacy technician with reasonable skill and safety.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

Commented [A234]: Clarity - I'm assu component of the application—you could this rule content and the rule below as new the application requirements above.

Commented [A235R234]: Clarity - Yo to specify this content as needing to be in t application, below, as presumably this rem during their many years of practice, not jus

20:51:29:09. Felony or misdemeanor crimes. The applicant shall declare any history of being charged with, convicted of, or entering a plea of guilty or no contest to, a felony or misdemeanor crime other than any traffic violation with a fine under one hundred dollars.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

Commented [A236]: Clarity - Same po
both the initial application and the renewal
might make it easier to repeal this section
content in the initial application section an
application section.

20:51:29:10. Sworn signature. The applicant shall sign and attest to the accuracy of the application under penalty of perjury and shall submit it to the board.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

Commented [A237]: Clarity - Same. Th
appears to be relevant to both initial and re
applications.

20:51:29:12. Registration fee. The fee for initial registration is twenty-five dollars. The renewal fee for ~~the~~ registration is twenty-five dollars. ~~Fees shall~~ The fee must be paid at the time the ~~new~~ initial application or the renewal application is submitted.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-11(13).

Commented [A238]: Clarity - "Initial a registration fees." ?

Commented [A239R238]: Clarity - Alt specify the fees in the relevant subdivision application and renewal application sectio section as unnecessary (but be sure to inclu cite for Law Implemented recommended b sections).

Commented [A240]: Clarity - Have to u here since the latter part of the sentence us application.

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Commented [A241]: Legality - This sec fee maximum for registration.

20:51:29:13. ~~Timeliness of initial application or renewal application~~ Expiration of registration -- Requirements for renewal -- Continuing education. An initial application may be denied if not received within the period specified in § 20:51:29:03. ~~A renewal application may be denied if not received by the~~ Registration as a pharmacy technician expires on October thirty-first ~~expiration date~~ and must be renewed annually. Any registration not renewed ~~before its expiration date~~ on or before October thirty-first is delinquent. To renew the registration, the pharmacy technician must submit to the board:

(1) A renewal application;

(2) The non-refundable renewal fee; and

(3) Proof of:

(a) Having completed six hours of continuing education within the last twenty-four months; or

(b) Current national certification from a pharmacy technician program accredited by the National Commission for Certifying Agencies.

An individual who continues employment as a pharmacy technician without a current registration may be subject to disciplinary actions as set forth in § 20:51:29:27.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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Commented [A242]: Clarity - Why not content to that section? It doesn't make se it ten sections further down the chapter. Th could primarily pertain to registration rene I am suggesting changes to this section as being moved.

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Commented [A243]: Clarity - and the t an initial application? Or what happens wh is delinquent?

Commented [A244R243]: Clarity - De to only be relevant for pharmacist licenses 23(2). It would appear otherwise that failu registration has an impact on the pharmaci that is where the consequence is meted out 20:51:29:14.

This chapter includes a disciplinary action registered technicians—ARSD 20:51:29:2 neither SDCL 36-11-20 or 36-11-26 relate technicians—they expressly authorize the pharmacists, not pharmacist technicians.

This issue was not brought up in the 2024 because there was confusion as to whether registration were the same thing. Now that clarified to mark them as distinct, these sta not apply in this instance.

Instead, the only thing that the Board migh that SDCL 36-11-2(22) envisions the techn "as permitted by the board." If the board is permit, it has the inherent power to not per only not permit if it has some substantive authority over the technician. The board n out better in statute, however!

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20:51:29:14. Registration certification. The pharmacy technician shall maintain a certificate of registration as a pharmacy technician. The pharmacist-in-charge of each pharmacy utilizing a pharmacy technician is responsible for verifying that any technician working in the pharmacy is registered with the board and compliant with all rules of this chapter. Any violation by the technician may be grounds for disciplinary action against the pharmacist-in-charge.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-2.2, 36-11-34.

Commented [A245]: Clarity - Is this sti the tech have to keep a physical certificate not, please strike and update the catchline.

Commented [A246]: Clarity - "employi

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20:51:29:15. Notification to the board. A registered pharmacy technician shall, within ten days of any change in the technician's name, address, or pharmacy employment status, report that change to the board.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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20:51:29:16. Training and utilization of pharmacy technicians. The pharmacist-in-charge of a pharmacy shall ensure that a registered pharmacy technician receives adequate training in the tasks performed by ~~pharmacy~~ technicians working at that pharmacy. A pharmacy utilizing a registered pharmacy technician shall develop, implement, and periodically review written policies and procedures for training and utilizing ~~pharmacy~~ technicians appropriate to the practice of pharmacy at that pharmacy. Each pharmacy shall specify the frequency of review in its policies. Each pharmacy shall document and maintain each registered pharmacy technician's training for the duration of employment. The pharmacy shall make its policies and procedures and documentation of registered pharmacy technician training available for inspection by the board.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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20:51:29:17. Identification of pharmacy technicians. A registered pharmacy technician shall, while on duty, wear a visible identification badge that clearly identifies the person as a pharmacy technician and includes the technician's first name.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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20:51:29:18. Misrepresentation prohibited. A registered pharmacy technician may not represent ~~himself or herself~~ themself as a pharmacist.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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20:51:29:19. Ratio. Up to three registered pharmacy technicians may be on duty in a pharmacy for every pharmacist on duty. A pharmacy intern does not count in this ratio.

Source: 31 SDR 35, effective September 19, 2004; 42 SDR 19, effective August 19, 2015; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

Cross-Reference: Number of interns, § 20:51:02:11.01.

Commented [A249]: Clarity - Since AR 20:51:29:19.02 appears to serve as an exce general rule, it should be signposted accor

"Except as provided in § 20:51:29:19.02, u registered pharmacy technicians…."

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20:51:29:19.02. Exception to ratio for hospital, mail order, and long-term care pharmacy. The maximum ratio of pharmacists to registered pharmacy technicians who may be on duty in a hospital, mail order, or long-term care pharmacy is determined by the pharmacist-in-charge. Regardless of the ratio, the following requirements must be met:

(1) Medication must be dispensed pursuant to a legal prescription;

(2) The technology must include tablet or product imaging or bar code scanning, to ensure accuracy in the prescription filling process;

(3) A role-based access software automation system that places stop points within the prescription filling process must be used, and the system must require a pharmacist's intervention before the prescription may move to the next step in the prescription dispensing process;

(4) Pharmacy software that screens and detects drug allergies, identifies drug interactions, and checks age-appropriate dosage ranges must be used;

(5) A pharmacist shall review clinically significant computer warnings of drug interactions, therapy duplications, and contraindications;

(6) Electronic surveillance technology must be used to control access or to provide continuous monitoring of all areas where drugs are stored or dispensed;

(7) All non-pharmacist personnel who input patient drug information into a computer or whose duties include receiving, packaging, or shipping of drugs~~.~~, or who have access to any areas where drugs are dispensed, must be registered as a pharmacy ~~technicians and meet the requirements of~~ technician in accordance with this chapter ~~20:51:29~~ or be registered as a pharmacy intern under chapter 20:51:02;

(8) In hospital and long-term care pharmacies, nursing personnel in facilities served by the pharmacy shall have telephone access to a pharmacist twenty-four hours a day, seven days a week. In mail order pharmacies, a patient shall have access to a pharmacist twenty-four hours a day, seven days a week on a dedicated pharmacist staff line;

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(9) Drug information must be readily available to pharmacists;

(10) A quality assurance program that identifies and evaluates dispensing errors, accompanied by a continuous quality improvement program that assures very high dispensing accuracy rates, must be in place;

(11) There must be written policies and procedures for all clerical, supportive, technical, and clinical pharmacy functions;

(12) There must be written policies and procedures for training personnel, including ongoing training programs for all personnel and documentation of that training for each employee; and

(13) There must be a monitoring program designed to prevent diversion of controlled substances. ~~This includes~~ The program must include perpetual inventory of all scheduled controlled drugs. Routine audits must be conducted to review purchases versus dispensing of controlled drugs to deter and detect diversion.

Source: 36 SDR 21, effective August 17, 2009; 42 SDR 19, effective August 19, 2015; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-19.2, 36-11-33.

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Commented [A252]: Clarity - Can this
E.g., the facility or pharmacy must maintai

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personnel? Or everyone?

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20:51:29:20. Delegation and supervision of technical functions. A pharmacist may delegate any technical dispensing ~~functions~~ function to a registered pharmacy technician provided the ~~pharmacist is on site supervising the performance of the delegated functions~~ function is performed under the immediate personal supervision of the pharmacist delegating the function. The pharmacist shall provide and document the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative.

The physical presence requirement of the pharmacist does not apply when utilizing an automated mechanical distribution device. The registered pharmacy technician may place medications into the automated mechanical distribution device that have been checked by the pharmacist. The pharmacist is not required to accompany the registered pharmacy technician when placing medications into the automated mechanical distribution device. The automated mechanical distribution device must be capable of printing out a record of medications filled by the registered pharmacy technician. The record must be checked and verified by the pharmacist daily.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(5)(13).

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-44.

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ARSD DM, pg. 15.

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below. Should that be used here?

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ensure that statute is being adhered to. The
the "immediate personal supervision" of th
the technician to perform the delegated tas
11-2(22). Just being on-site does not meet
meaning of "immediate personal supervisi
Moreover, insofar as an intern is permitted
pharmacy technician functions, the intern
prescription "in the presence of the pharma
11-25. That further underscores the need t
statute. The authority you cite below is an
authority that underscores the need for this

The automated distribution machine is not
arguably, as defined in chapter 36-11, and
paragraph is okay.

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statute that approximates this is the "auton
machine". Indeed, some of the references
mechanical distribution device" in this rul
proposed by the agency for change to "aut
machine." Should that be done in this para

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mechanical distribution devices only relev
telepharmacy? If so, SDCL 36-11-72(6) ap
necessary cite for General Authority.

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prohibits the dispensing of prescriptions ex
personal supervision of pharmacist. Does t
paragraph of this rule conflict with that sta
removes the physical presence requiremen

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

(1) Performing packaging, manipulative, or repetitive tasks relating to the processing of a prescription or medication order in a licensed pharmacy;

(2) Accepting prescription 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;

(5) Inspecting drug supplies provided and controlled by a South Dakota licensed pharmacy, including drug supplies maintained in an automated mechanical distribution device, emergency medical room, ambulance, long-term care facility, hospital nursing unit, or hospice facility; and

(6) Assisting the pharmacist with the preparation of medications for administration to the patient topically, by injection, or by other approved methods.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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list exhaustive by using "are". Otherwise,
that more functions could be delegated tha
described in this list.

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confusion by specifying tasks that the phar
not perform. Generally, it should be assum
not specified in rule as permitted, are tasks
performed. But because of this word choic
20:51:29:22, there is substantial confusion

ARSD 20:51:28:02.02 provides an additio
pharmacy techs may perform, and that is n
Ideally, this would provide an exhaustive l

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20:51:29:20.

20:51:29:22. Tasks a pharmacy technician may not perform. A registered pharmacy technician may not:

(1) Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order;

(2) Conduct prospective drug use review or evaluate a patient's medication record for purposes identified in § 20:51:25:02;

(3) Provide final verification of automated dispensing medication fill records for accuracy and completeness;

(4) Make decisions that require a pharmacist's professional judgment such as interpreting new orders, applying information, or making product selection for drugs that are substitutable;

(5) Accept new verbal prescription medication orders communicated to the pharmacy by a prescriber or the prescriber's agent; or

(6) Provide pharmaceutical services in a pharmacy without a pharmacist being present, except as authorized in chapter 20:51:30.

A violation of this section may be grounds for disciplinary action as provided in § 20:51:29:27.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22)~~, 36-11-26~~.

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Commented [A264]: Clarity - Example avoided.

Commented [A265R264]: Style - If ex absolutely necessary, then use an Example in ARSD DM, pg. 21.

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20:51:29:23. Misrepresentative deeds. A registered pharmacy technician may not make any statement tending to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in a pharmacy.

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Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

20:51:29:24. Confidentiality. In the absence of express written consent from the patient or a written order or direction of a court, except where the best interests of the patient require, a registered pharmacy technician may not divulge or reveal to any person, other than as outlined in SDCL 36-11-69, any of the following information:

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(1) The contents of any prescription drug order or medication, the therapeutic effect thereof, or the nature of professional pharmaceutical services rendered to the patient;

(2) The nature, extent, or degree of illness suffered by the patient; or

(3) Any medical information furnished by the prescriber.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-69.

20:51:29:25. Illegal or unethical behavior. A registered pharmacy technician may not exhibit illegal or unethical behavior in connection with the technician's pharmacy employment. Illegal or unethical behavior includes~~:~~ verbal or physical abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, profanity, indecent or obscene conduct, and theft. A violation of this section may be grounds for disciplinary action as provided for in § 20:51:29:27.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22)~~, 36-11-26~~.

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Commented [A268]: Clarity - Same as list exhaustive?

Commented [A269R268]: Legality - It critical that a list of grounds for adverse e be exhaustive and clear.

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Commented [A271R270]: Legality - S comment on 20:51:29:13.

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20:51:29:26. Denial of registration. The board may deny an application for registration as a pharmacy technician for any violation of:

(1) The laws of this state, another state, or the United States, relating to prescription drugs, controlled substances, or nonprescription drugs; or

(2) This chapter.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22)~~, 36-11-26~~.

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20:51:29:27. Disciplinary actions. For violations of this chapter, the board may:

(1) Revoke a pharmacy technician registration;

(2) Suspend a pharmacy technician registration until further order of the board or for a specified period;

(3) Not renew a pharmacy technician registration;

(4) Prohibit permanently, until further order of the board, or for a specified period, the engaging in specified procedures, methods, or acts;

(5) Impose a probationary period;

(6) Refer the pharmacy technician to the Health Professionals' Assistance Program; or

(7) Issue a letter of concern or public reprimand.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-2A-2, 36-2A-6, 36-11-2~~(26)~~(22)~~, 36-11-26~~.

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Commented [A275R274]: Style - Agre capitalized in SDCL chapter 36-2A, so it s capitalized here as a proper noun. ARSD I

Commented [A276]: Legality - Same.

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CHAPTER 20:51:30

TELEPHARMACY

Section

20:51:30:03. Ownership or control by pharmacist required. The board may not issue a ~~permit~~ license to conduct a remote pharmacy to any pharmacist applicant unless ~~such~~ the pharmacist applicant is an owner, or part owner, of the place of business from which the pharmacist will practice telepharmacy, or unless the non-pharmacist owner of the place of business from which the pharmacist will practice telepharmacy files an affidavit on a form prescribed by the board delegating full and complete authority to the pharmacist applicant to be in active management of the place of business for the license year ending June ~~30~~ thirtieth.

Source: 35 SDR 183, effective February 2, 2009.

General Authority: SDCL 36-11-11(1), 36-11-72(1).

Law Implemented: SDCL 36-11-34, 36-11-72.

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Commented [A277]: Clarity - Could a c the affidavit in 36-11-34 be made here to s

Commented [A278]: Legality - The rel of this section should be cited.

20:51:30:09. Restricted ~~area posted~~ access to remote pharmacy. ~~The remote pharmacy dispensing area shall be posted as a restricted area. Only pharmacy technicians or pharmacy interns employed directly and involved in processing prescriptions are permitted in the dispensing area.~~ There must be restricted access to the ~~restricted area~~ remote pharmacy. The security system at the remote pharmacy must allow for tracking of each entry into the pharmacy. The pharmacist-in-charge shall review the log of entries at least weekly.

Source: 35 SDR 183, effective February 2, 2009.

General Authority: SDCL 36-11-11(1), 36-11-72(2)~~-~~(5).

Law Implemented: SDCL 36-11-72(2)~~-~~(5).

Commented [A279]: Clarity - What do mean? Restricted access to who?

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Commented [A280]: Legality - There is inform the limiting guidance or policy for pharmacies. Similar to the pharmacy techn board may want to consider adding more r statutory bones for remote pharmacies. Per could be added here.

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20:51:30:12. Technician and intern staffing requirements. Each remote pharmacy must be staffed with registered certified pharmacy technicians or registered pharmacy interns. A registered pharmacy technician working at a remote pharmacy without an onsite pharmacist, pharmacy intern, or experienced telepharmacy technician, must have a minimum of ~~two~~ one thousand hours of experience as a registered pharmacy technician in accordance with chapter 20:51:29 and ~~shall~~ must be certified in accordance with § 20:51:29:06. ~~One thousand~~ Five hundred hours of this experience must be in a telepharmacy with an onsite pharmacist, pharmacy intern, or another registered pharmacy technician meeting the experience requirements for technicians in this section. ~~An~~ A pharmacy intern may work at a remote pharmacy if the intern has at least five hundred hours of experience as a registered pharmacy intern in accordance with chapter 20:51:02.

Source: 35 SDR 183, effective February 2, 2009; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(13), 36-11-72(3).

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-25, 36-11-71.

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Commented [A282]: Clarity - By inclu here, you are indicating that the technician national certification. Is that the intent? Gi recommendations provided above, it woul "a registered pharmacy technician, who ha national certification from a pharmacy tech accredited by the National Commission fo Agencies,…"

Commented [A283]: Clarity - Singular unless multiple technicians or interns are r

Commented [A284]: Clarity - Note pre interns who are registered vs. interns who

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Commented [A285]: Clarity - Experien standards? A certain number of years or ho this term hasn't been used in the chapter th different than the normal registered tech? mean someone who has completed the hou follows?

Commented [A286R285]: Clarity - I ha year "another pharmacy technician meetin requirements for technicians in this sectio to be what this was getting at, but it was n

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20:51:30:13. Pharmacist-to-technician ratio. The pharmacist on duty at a central pharmacy may supervise no more than the number of registered pharmacy technicians allowed in accordance with § 20:51:29:19. The total number of allowed registered pharmacy technicians may be divided between the central pharmacy and the remote pharmacy in any manner. However, each remote pharmacy must have at least one pharmacy technician or pharmacy intern, ~~that~~ who meets the ~~criteria~~ requirements in § 20:51:30:12, on duty when it is open.

Source: 35 SDR 183, effective February 2, 2009.

General Authority: SDCL 36-11-11(1), 36-11-72(3).

Law Implemented: SDCL ~~36-11-72(3),~~ 36-11-2(22), 36-11-71.

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If a pharmacist is onsite at the remote phar
least one pharmacy tech have to have the e
certification as outlined by that section? A
seem to apply to interns, as they have to ha
regardless to work in a remote pharmacy.
trying to say that a remote pharmacy needs
one intern to be open? If so, this content sh
the section above in the appropriately title
requirements" rule.

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here.

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only provides the subject area in which the
authorized to make rules (i.e., General Aut
provide intelligible standards or limitation
authority, within that subject area, should

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20:51:30:15. Requirements for prescription orders. Only a ~~registered~~ pharmacist may take a verbal prescription order. A registered pharmacy technician at the remote pharmacy may not accept verbal orders for new prescriptions~~,~~ but may accept written orders. A written order for a new prescription may be entered at the central pharmacy or the remote pharmacy. The pharmacist must approve or override all drug utilization review alerts.

Source: 35 SDR 183, effective February 2, 2009.

General Authority: SDCL 36-11-11(1), 36-11-72(5).

Law Implemented: SDCL ~~36-11-72(5),~~ 36-11-2.2, 36-11-2(22), 36-11-71.

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20:51:30:16. Requirements for operation. The following requirements ~~must be adhered to~~ apply when operating a remote pharmacy:

(1) The remote pharmacy may only be open if a computer link, video link, and audio link with the central pharmacy are functioning properly. If any link is not functioning properly, the remote pharmacy must be closed unless a pharmacist is working at the remote pharmacy;

(2) No remote pharmacy may be open when the central pharmacy is closed, unless a ~~licensed~~ pharmacist is working at the remote pharmacy;

(3) Any prescription filled at the remote pharmacy must be profiled, reviewed, and interpreted by a pharmacist at the central pharmacy before the prescription is dispensed;

(4) Any remotely dispensed prescriptions must have a label properly prepared in accordance with § 20:51:05:21 attached to the final drug container before the pharmacist ~~certifies~~ verifies the dispensing process. This prescription ~~certification~~ verification process must be done in real time. All prescription ~~certification~~ verification must be documented in the computer record. The computer must be capable of carrying the initials of the registered pharmacy technician preparing the prescription and the pharmacist verifying the prescription. Verification is required for both new prescriptions and refills;

(5) When the patient receives a prescription, the pharmacist must use audiovisual communication to counsel the patient regarding use of the prescription being dispensed. Counseling is required only for new prescriptions. The pharmacist must meet the counseling standards in accordance with § 20:51:25:04; and

(6) The remote pharmacy must maintain a log, signed by the patient, that documents a patient's refusal for counseling by the pharmacist.

Source: 35 SDR 183, effective February 2, 2009.

General Authority: SDCL 36-11-11(1), 36-11-72(2), (3), (4), (5).

Law Implemented: SDCL ~~36-11-72(2),(3),(4),(5)~~ 36-11-2.2, 36-11-2(22), 36-11-71.

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20:51:30:18. Use of automated prescription dispensing device. If the remote pharmacy uses an automated mechanical dispensing device, the stocking and loading of this device must either be checked by a pharmacist, prior to use, or employ a secure bar coding system or its equivalent. Policies and procedures consistent with § 20:51:17:02 regarding the operation of the automated mechanical ~~distribution system~~ dispensing device must be developed and submitted to the board for consideration. After approval, these policies and procedures must be available at both the central pharmacy and the remote pharmacy.

Source: 35 SDR 183, effective February 2, 2009; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)~~,(6),~~ 36-11-72(5)(6).

Law Implemented: SDCL ~~36-11-11(6), 36-11-72(6)~~ 36-11-2.2, 36-11-71.

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Commented [A297]: Legality - I don't subdivision is relevant to this section for e Authority or Law Implemented?

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20:51:31:32. Compounding and hazardous drug handling standards -- United States Pharmacopeia compounding standards implemented by reference. All sterile compounding, nonsterile compounding, and repackaging must be handled in accordance with federal law, this chapter, and the United States Pharmacopeia–National Formulary (February 1, 2024), General Chapter 797 *Pharmaceutical Compounding – Sterile Preparations,* General Chapter 795 *Pharmaceutical Compounding – Nonsterile Preparations,* General Chapter 800 *Hazardous Drugs – Handling in Healthcare Settings,* and General Chapter 825 *Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*.

Source: 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3)(8).

Law Implemented: SDCL 36-11-2.2(3), 36-11-11(3)(8), 36-11-46.

Reference: United States Pharmacopeia--Compounding Compendium (February 1, 2024), available at https://online.uspnf.com/uspnf. Cost: ~~$800~~ $250 for individual user.

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Formulary is used. Why is there a differen

Commented [A299R298]: Clarity - Ma
in last year's rulemaking. It was not revise

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hyperlink, but please ensure it is not under
erroneously indicate new material.

20:51:31:33. Policy and procedure manual. The pharmacist-in-charge must prepare and maintain a policy and procedure manual for compounding practices. The policy and procedure manual must include a quality assurance program, and all applicable United States Pharmacopeia requirements, and be available for inspection by the board.

Source: 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3)(8).

Law Implemented: SDCL 36-11-2.2(3), 36-11-46.

Reference: United States Pharmacopeia--Compounding Compendium (February 1, 2024), available at https://online.uspnf.com/uspnf. Cost: ~~$800~~ $250 for individual user.

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Commented [A301]: Style/form - Same

20:51:31:34. Compounding requirements. Any pharmacy that engages in compounding must adhere to physical, equipment, and environmental requirements established by United States Pharmacopeia. Pharmacy compounding staff shall have access to current reference materials applicable to compounding.

Source: 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3)(8).

Law Implemented: SDCL 36-11-2.2(3), 36-11-46.

Reference: United States Pharmacopeia--Compounding Compendium (February 1, 2024), available at https://online.uspnf.com/uspnf. Cost: ~~$800~~ $250 for individual user.

Commented [A302]: Legality - Is this r 11-46? If you retain, this must follow the l format as noted above.

Commented [A303R302]: Legality - N issue last year. Was not addressed in that r

Commented [A304]: Clarity - Who has access? The pharmacy?

Commented [A305]: Same.

20:51:33:01. Applicability. The following procedure applies to complaints about holders of the licenses, ~~permits,~~ registrations, or certificates regulated by the Board of Pharmacy.

Source: 45 SDR 86, effective December 24, 2018.

General Authority: SDCL 36-11-11(1)~~(2)~~(3)(10)~~and~~ (13), 36-11A-14.

Law Implemented: SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26~~, 36-11-28, 36-11-29~~, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48~~, 36-11-49~~, 36-11-65~~, 36-11A-14~~.

Commented [A306]: Clarity - This is va procedure follows? Do I need to check to s of the statutes in this section pertain to pro do not?

Recommend: "This chapter applies to com

Commented [A307]: Clarity - The shor been used throughout.

Commented [A308]: Legality - This sec relate to the "sanitation of persons and esta licensed under" this chapter.

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Commented [A309]: Legality - Many o not directly apply to the procedure or com those regulated by the board—just statutes violated. Consider striking the citations tha

Nonetheless, doesn't SDCL chapter 36-1C uniform complaint process? Wouldn't that all the entities regulated by the board, inclu wholesale drug distributers?

Commented [A310]: Legality - This is

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20:51:33:02. Complaints. The executive secretary may initiate an investigation based on a written complaint. Any person filing a complaint shall submit the complaint in writing to the executive secretary. A complaint is not a public record. The executive secretary shall dismiss any complaint that concerns matters over which the board does not have jurisdiction, and shall notify the complainant of that action. The executive secretary may also initiate an investigation upon reasonable suspicion that a licensee or registrant is in violation of any applicable standard for professional conduct.

Source: 45 SDR 86, effective December 24, 2018.

General Authority: SDCL 36-11-11(1)~~(2)~~(3)(10)~~ and~~ (13).

Law Implemented: SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26~~, 36-11-28, 36-11-29~~, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48~~, 36-11-49~~, 36-11-65, 36-11A-14.

Commented [A311]: Legality - Again, section square with SDCL 36-1C-2 and SD

Commented [A312]: Legality - SDCL the administrator "shall assign an investiga after serving a copy of the complaint to the complaint and after allowing twenty days

Commented [A313]: Clarity - What abo holds a certificate?

Commented [A314R313]: Legality - If intended to be included, then SDCL 36-11 cited as General Authority and as Law Imp

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Commented [A315]: Legality - Same c

20:51:33:03. Investigations. The executive secretary shall initiate an investigation of a complaint by notifying the license, registration, or certificate holder of the complaint and obtaining a response to the complaint. If the executive secretary determines that the complaint concerns compliance with licensing standards and requirements, the executive secretary shall investigate the complaint. The notice ~~shall~~ must be in writing and ~~shall~~ must include a statement that the ~~licensure, licensee, or registrant~~ license, registration, or certificate holder is entitled to due process rights, including the right to notice and an opportunity to be heard and to be represented by counsel. The executive secretary may appoint a board member to assist in the investigation.

Source: 45 SDR 86, effective December 24, 2018.

General Authority: SDCL 36-11-11(1)~~(2)~~(3)(10)~~and~~ (13), 36-11A-14.

Law Implemented: SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26~~, 36-11-28, 36-11-29~~, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48~~, 36-11-49~~, 36-11-65~~, 36-11A-14~~.

Commented [A316]: Legality - Same c re: chapter 36-1C.

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Commented [A317]: Legality - As a ce referenced then SDCL 36-11-25 should be General Authority and Law Implemented.

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Commented [A318]: Legality - Same.

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20:51:33:04. Completion of complaint investigation. Upon completion of a complaint investigation, the executive secretary may:

(1) Dismiss the complaint as unsubstantiated or requiring no further action. Dismissal of a complaint is not a public record;

(2) Issue a letter of concern, that ~~shall~~ must be placed in the licensee's or registrant's permanent records. A letter of concern is not a public record;

(3) Recommend the board issue the licensee or registrant a public reprimand;

(4) Recommend the board re-open and modify the license to include compliance with specified terms and conditions; or

(5) Recommend the board suspend or revoke the license.

If the executive secretary recommends issuance of a public reprimand, re-opening and modification, or suspension or revocation of the license, registration, or certificate held by the licensee or registrant, the executive secretary ~~shall~~ must notify the licensee or registrant of the right to contest the recommendation. If contested, the executive secretary ~~shall~~ must issue a petition for hearing that sets out the recommendation and the reasons for the recommendation and initiates a contested case hearing. A copy of the petition for hearing ~~shall~~ must be sent to the licensee or registrant. The executive secretary and licensee or registrant may enter into a settlement agreement concerning the recommendation to be made to the board.

Source: 45 SDR 86, effective December 24, 2018.

General Authority: SDCL 36-11-11(1)~~(2)~~(3)(10)~~and~~ (13).

Law Implemented: SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26~~, 36-11-28, 36-11-29~~, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48~~, 36-11-49~~, 36-11-65, 36-11A-14.

Commented [A319]: Legality - Same c

Commented [A320]: Clarity - what of

Commented [A321R320]: Legality - If intended to be included, then SDCL 36-11 cited as General Authority and as Law Imp

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Commented [A322]: Style - Action req condition of something. ARSD DM, pg. 14

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20:51:33:05. Status of complainant. The complainant is not a party to any contested case hearing resulting from the executive secretary's investigation of a complaint, although the complainant may be called as a witness in the hearing. The executive secretary shall notify a complainant of any public final agency action taken as a result of a complaint.

Source: 45 SDR 86, effective December 24, 2018.

General Authority: SDCL 36-11-11(1)~~(2)~~(3)(10)~~ and~~ (13).

Law Implemented: SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26~~, 36-11-28, 36-11-29~~, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48~~, 36-11-49~~, 36-11-65, 36-11A-14.

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Commented [A324]: Legality - Same.

20:51:33:06. Effect of failure to renew during investigation. The holder of a license, registration, or certificate may choose not to renew the license, registration, or certificate after a complaint investigation has been initiated by the executive secretary. A failure to renew after an investigation has been initiated ~~shall~~ must be reported as "withdrawn under investigation" in the board's permanent license files and in any national databases to which the board is required to report licensure action.

Source: 45 SDR 86, effective December 24, 2018.

General Authority: SDCL 36-11-11(1)~~(2)~~(3)(10)~~and~~ (13).

Law Implemented: SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26~~, 36-11-28, 36-11-29~~, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48~~, 36-11-49~~, 36-11-65, 36-11A-14.

Commented [A325]: Clarity - Technica is not the same as someone actively withdr

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Commented [A326]: Clarity - Should th registration and certificate files for consist just permanent files?

Commented [A327]: Legality - As a ce referenced then SDCL 36-11-25 should be General Authority and Law Implemented.

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Commented [A328]: Legality - Same as

20:51:36:02. License required. Any pharmacy acting as a central fill pharmacy in this state must be ~~permitted~~ licensed pursuant to SDCL 36-11-32 and not ~~permitted~~ licensed as a pharmacy under SDCL 36-11-33. Any central fill pharmacy located outside the state must be licensed as a non-resident pharmacy. Any originating pharmacy located in this state must be ~~permitted~~ licensed as a full-time pharmacy.

Commented [A329]: Clarity - Recomm statutory citation as is done above.

Source: 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(3).

Law Implemented: SDCL 36-11-19.2, 36-11-19.3, 36-11-30.

20:67:02:01. Application and fee. A wholesale or other distributor must apply each year to the board, electronically or on a form supplied by the ~~secretary of the~~ board, for a license to engage in the distribution of prescription drugs. Each application ~~shall~~ must be accompanied by a license fee of ~~$200~~ five hundred dollars.

Source: 18 SDR 95, effective November 25, 1991; 24 SDR 160, effective May 26, 1998; 45 SDR 86, effective December 24, 2018.

General Authority: SDCL 36-11A-14~~(1),(6)~~.

Law Implemented: SDCL 36-11A-7, 36-11A-8.

Commented [A330]: Legality - Just a n
appears to be an obsolete cross reference i
subdivision (1) to SDCL 36-11A-3 (which
been repealed in 2007).

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Commented [A331]: Legality - When s
agency to modify a rule section with preci
revisions, those revisions need to be follow
The edits to the left address this issue.

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20:67:02:10. Out-of-state wholesale or other drug distributor application -- Other state license required. Out-of-state wholesale or other drug distributors must meet the application and fee requirements of this chapter and must also submit a copy of their wholesale drug distributor's license or its equivalent from the state in which the distributor is located if a license is issued by that state. Any applicant located outside of the state must provide a copy of ~~a~~ the most recent inspection that has been conducted within the last four years by the facilities home state licensing agency or any other agency approved by the board. ~~If there are any~~ Any findings or deficiencies that are observed during the inspection, and an explanation of corrections, must be included with the application.

Source: 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

General Authority: SDCL 36-11A-14(1).

Law Implemented: SDCL 36-11A-7, 36-11A-11, 36-11A-28.

Commented [A332]: Style/form - The b sentence starts with plural form, and it swi here. Singular is preferred, but whichever consistent in the sentence.

Commented [A333]: Clarity - The first sentence says the most recent inspection, a the last four years. If the most recent inspe ago or beyond, do they not have to submit recent inspection seems to suffice.

Commented [A334R333]: Legality - H requirement square with SDCL 36-11A-16 authorization that a satisfactory inspection years old means no further inspections are period of time to be determined by the boa

Shouldn't that SDCL section also be cited Implemented?

Commented [A335]: Clarity - Please us terminology and proper grammar.

Commented [A336]: Clarity - What oth approved by the board? Are there any stan approval? Is this addressed somewhere els distributors?

Commented [A337]: Clarity - "taken by

Commented [A338]: Legality - Wouldn appropriate, since that statute specifically inspections?

DIRECTIONS FOR SUBMITTING THE FINAL DRAFT

Rules Review Meeting Schedule for the 2025 Interim: The Interim Rules Review Committee will meet April 8, May 6, June 10, July 15, August 19, September 9, and October 7. Meeting notices will be posted on the LRC website and at the Capitol.

A. Committee: The following materials must be served on the Committee at least seven calendar days before the committee meeting via first-class mail, e-mail, or both:

1. Form 12 – Affidavit and all its referenced documents (for final rules, please three-hole punch and number by page the final rules):

   a. Form 10 – Minutes of Public Hearing;
   b. A record of written comments;
   c. Form 14 – Small Business Impact Statement;
   d. Form 5 – Fiscal Note;
   e. For any rules that increase a fee, per SDCL 1-26-4.8, a completed Form 17;
   f. For any rules prescribing new standards or requirements for building or remodeling a residential structure based on a model code, the Form 16 – Housing Cost Impact Statement; and
   g. The final rules as adopted;

2. Form 15 – Rules Presentation Format;

3. First draft of proposed rules containing LRC recommendations for style, form, clarity, and legality; and

4. Letter from the LRC to the agency.

B. Legislative Research Council: The following materials must be submitted to the LRC at least seven calendar days before the committee meeting:

1. Final draft of adopted rules, double-spaced and containing only amended, repealed, or adopted rules, and showing overstrikes and underscores;

2. Original Form 11; and

3. Copies of:

   a. Form 10 – Minutes of Public Hearing
   b. A record of written comments;
   c. Form 12 – Affidavit of Service;
   d. Form 15 - Rules Presentation Format; and
   e. Form 17 – Agency Financial Resources, if applicable.

C. Office of the Secretary of State: Following Committee hearing, each agency must complete and sign all documents before filing:

1. Form 13 - Certificate of rule completion;

2. Final draft of the adopted rules; and

3. Form 11 (per Secretary's request).

FORM 15

Rules Presentation Format

Department/Board/Commission Name _____

Please complete these questions to show that the SDCL 1-26 rule-making process is complete.

Use this format to organize your presentation to the Committee.

- Approval to proceed? Yes _____ No _____ Date _____
- Date of public hearing _____
- Date proposed rules and supporting documents submitted to the LRC and the Bureau of Finance and Management _____
  - any publication incorporated by reference;
  - the fiscal note;
  - the impact statement on small business; and
  - the notice of hearing.
- Date and name of newspapers in which the notice of public hearing was published:
  - Date _____ Newspaper _____
  - Date _____ Newspaper _____
  - Date _____ Newspaper _____
- Summary of how, when, and number of interested persons, if any, were contacted.
  _____
  _____
  _____
- Page numbers in the minutes where the agency considered amendments, data, opinions, or arguments regarding the proposed rules, along with any changes and final action.
  _____
- For any rule implementing a bill from a preceding session, the number of the bill:
  _____
- Date final rules and supporting documents submitted to the LRC and the Committee
  _____