2025 South Dakota Legislature

House Bill 1016

AMENDMENT 1016C FOR THE HOUSE APPROPRIATIONS ENGROSSED BILL

1 An Act to revise provisions related to pharmacy and to increase fees.

2 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF SOUTH DAKOTA:

3 Section 1. That § 13-33A-4 be AMENDED:

13-33A-4. Any school may acquire and maintain a stock of epinephrine autoinjectors pursuant to a prescription issued by an authorized health care provider for use
in an emergency situation of a severe allergic reaction causing anaphylaxis. The provisions
of this section are not subject to the prescription requirements in subdivision 36-11-2(21)
chapter 36-11.

9 Section 2. That § 36-11-2 be AMENDED:

- 10 **36-11-2.** Terms used in this chapter mean:
- 11 (1) "Association," the South Dakota Pharmacists Association;
- 12 (2) "Biological product," as defined in 42 U.S.C. <u>§</u>262(i), as of (January 1, 2018);
- 13 (3)(2) "Board," or "board of pharmacy," the State Board of Pharmacy in South Dakota;
- (4)(3) "Brand name," the proprietary or registered trademark name given to a drug
 product by its manufacturer, labeler, or distributor and placed on the drug or on
 its container, label, or wrapping at the time of packaging;
- 17 (5) "Chemicals," the chemical materials or medicine;
- (6)(4) "Compounding," the preparation, mixing, assembling, packaging, or labeling of a drug or drug device as the result of a practitioner's prescription drug order or an initiative based on the pharmacist/patient/practitioner relationship in the course of professional practice or for the purpose of or as an incident to research, teaching, or chemical analysis and not for sale or dispensing. The term also includes the preparation of drug or drug devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

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(7)(5) "Delivery," the actual, constructive, or attempted transfer of a drug or drug device 1 2 from one person to another, whether or not for a consideration; 3 (8)(6) "Dispense" or "Dispensing," the preparation and delivery of a drug to a patient or 4 a patient's agent pursuant to a prescription drug order in a suitable container with 5 appropriate labeling for subsequent administration to or use by a patient. The term 6 includes preparation of labels for drug devices if the labeling is related to the 7 dosage and administration of drugs; 8 (9) (7) "Distributing," the delivery of a drug or drug device other than by administration 9 or dispensing; "Drug administration," the direct application of a drug or drug device by 10 (10)(8) 11 injection, inhalation, ingestion, or any other means to the body of a patient or 12 research subject; 13 "Drug device," equipment, process, biotechnological entity, diagnostic agent, (11)(9) or other product used in combination with a drug to provide effective management 14 15 of medication regimens; 16 (12) "Drug utilization review program," any program operated solely or partially as a 17 professional standards review organization whose purpose is to educate 18 pharmacists and practitioners on severe adverse reactions to drugs, therapeutic 19 appropriateness, overutilization and underutilization, appropriate use of generic 20 products, therapeutic duplication, drug-disease contraindications, drug-drug 21 interactions, incorrect drug dosage or duration of drug treatment, drug allergy 22 interactions and clinical abuse or misuse, as well as to identify and reduce the 23 frequency of patterns of potential and actual fraud, abuse, gross overuse, 24 inappropriate care or medically unnecessary care associated with specific drugs or 25 groups of drugs among practitioners, pharmacists and patients; 26 (13) "Equivalent drug product," a drug product, other than a biological product, that 27 is considered to be therapeutically equivalent to other pharmaceutically equivalent 28 products as determined by the latest edition of Approved Drug Products with 29 Therapeutic Equivalence Evaluations, as adopted by the board through rules 30 promulgated pursuant to chapter 1-26; 31 (14)(11) "Interchangeable biological product," a biological product that the U.S. United 32 States Food and Drug Administration either has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. § 262(k)(4), as of (January 33 1, 2018), or has determined is therapeutically equivalent, as set forth in the latest 34 35 edition of, or any supplement to, the Food and Drug Administration's Approved

1Drug Products with Therapeutic Equivalence Evaluations-publication as adopted by2the board through rules promulgated pursuant to chapter 1-26;

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(15)(12) "Labeling," the process of preparing and affixing a label to any drug or drug device container exclusive of the labeling by the manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or drug device;

- 7 (16) "Medical device," an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any 8 9 component, part or accessory, that is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease 10 in man or other animals or is intended to affect the structure or any function of the 11 12 body of man or other animals, that does not achieve any of its principal intended 13 purposes through chemical action within or on the body of man or other animals 14 and that is not dependent upon being metabolized for achievement of any of its 15 principal intended purposes;
- (17)(13) "Medicines," drugs or chemicals, or their preparations, in suitable form for the
 prevention, relief, or cure of diseases when used either internally or externally by
 man or for animals;
- (18)(14) "Nonprescription drugs," drugs that are labeled for use by the general public in 19 accordance with § 502 of the Federal Food, Drug and Cosmetic Act as amended 20 21 through January 1, 1997, 21 U.S.C. § 352 (January 1, 2025), and may be sold 22 without a prescription drug order in accordance with § 503 of the Federal Food, Drug and Cosmetic Act as amended through January 1, 1997 21 U.S.C. § 353 23 24 (January 1, 2025). The term does not include drugs which that are required by 25 federal law to bear the statement, "Caution: federal law prohibits dispensing 26 without prescription," drugs intended for human use by hypodermic injection, or 27 animal remedies regulated by chapter 39-18;
- (19)(15) "Patient counseling," oral communication by the pharmacist of information to
 the patient or caregiver, as defined in rules promulgated pursuant to chapter 1-26,
 to improve therapy by ensuring proper use of drugs and drug devices;
- 31 (20)(16) "Pharmaceutical care," provision of drug therapy and other pharmaceutical
 32 patient care services intended to achieve outcomes related to <u>cure curing</u> or
 33 prevention of preventing a disease, <u>elimination eliminating</u> or <u>reduction of reducing</u>
 34 a patient's symptoms, or arresting or slowing-of a disease process;

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1	(21)<u>(17)</u>	"Pharmacist," a person licensed by the board to engage in the practice of
2	ph	armacy;
3	(22)<u>(18)</u>	"Pharmacy," any place of business within or outside this state licensed by the
4	be	ard where drugs are dispensed and pharmaceutical care is provided to residents
5	of	this state;
6	(23)<u>(19)</u>	"Practitioner," a person licensed, registered, or otherwise authorized by the
7	ju	risdiction in which the person is practicing to prescribe drugs in the course of
8	pr	ofessional practice;
9	(24)<u>(20)</u>	"Prescription drug order," a written or oral order of a practitioner for a drug or
10	dr	ug device for a specific patient;
11	(25)<u>(</u>21)	"Proper name," the nonproprietary name for a biological product designated by
12	th	e U.S. United States Food and Drug Administration license for use upon each
13	ра	ckage of the product; <u>and</u>
14	(26)<u>(</u>22)	"Registered pharmacy technician," a person registered by the board who is
15	en	nployed by a pharmacy to assist licensed pharmacists in the practice of pharmacy
16	by	performing specific tasks delegated by and under the immediate personal
17	su	pervision and control of a licensed pharmacist, as permitted by the board;
18	(27) "R	etail place of business," any place where merchandise is sold at retail and from
19	wł	nich original packages of nonprescription drugs are sold or taken to be sold at
20	rei	t ail;
21	(28) "R	everse distributor," any person or business registered with the Drug Enforcement
22	Ac	Iministration that accepts drug products from vendors and returns the drug
23	pr	oducts to manufacturers for credit or destruction.
24	Section 3 T	hat § 36-11-2.1 be AMENDED:
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25	36	5-11-2.1. Drugs For the purpose of this chapter, "drugs" are defined as follows:
26	(1) Ar	ticles recognized in the official United States Pharmacopoeia or the official
27	Na	itional Formulary, as adopted by the board of pharmacy through rules
28	pr	omulgated pursuant to chapter 1-26, or recognized in the official Homeopathic
29	Ph	armacopoeia of the United States as in effect on January 1, 1993;
30	(2) Ar	ticles intended for use in the diagnosis, cure, mitigation, treatment, or prevention
31	of	disease in humans or other animals;
32	(3) Ar	ticles $($ _other than food $)_{L}$ intended to affect the structure or any functions of the
33	hu	man body; and
34	(4) Ar	ticles intended for use as a component of any articles specified in this section.

1 The term "drugs" excludes medical devices. 2 For the purposes of this section, "medical device" means an instrument, apparatus, 3 implement, machine, contrivance, implant, in vitro reagent, or other similar or related 4 article, including any component, part, or accessory, that is intended for use in the 5 diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease in humans or animals, or is intended to affect the structure or any function of 6 7 the body of humans or animals, that does not achieve any of its principal intended 8 purposes through chemical action within or on the body of humans or animals and that is 9 not dependent upon being metabolized for achievement of any of its principal intended

10 <u>purposes.</u>

11 Section 4. That § 36-11-5 be AMENDED:

36-11-5. The Board of Pharmacy board shall hold meetings for the examination of
 applicants for licensure and registration, and the transaction of such other business as
 shall pertain that pertains to its duties. Special meetings of the board may be held
 whenever it shall be deemed necessary by a majority of the members thereof board. Two
 Three members of such the board shall constitute constitutes a quorum.

17 Section 5. That § 36-11-13 be AMENDED:

36-11-13. It is a Class 2 misdemeanor for any person other than a pharmacist
 registered under the laws of South Dakota to engage in the practice of pharmacy, except
 as provided by § 36-11-14.

21 Section 6. That § 36-11-15 be AMENDED:

36-11-15. Any person, other than a registered pharmacist, who compounds or
 dispenses drugs, medicines, or poisons, or who keeps a pharmacy or store for retailing or
 compounding medicines, or who takes, uses, or exhibits the title of a registered
 pharmacist, is guilty of a Class 2 misdemeanor.

26 Section 7. That § 36-11-16 be AMENDED:

27 **36-11-16.** Any person of The board shall issue a license to practice pharmacy to

- 28 <u>an individual who:</u>
- 29 (1) Submits an application prescribed by the board;

Submits an application fee set by the board through rules promulgated in 1 (2) 2 accordance with chapter 1-26, but not exceeding thirty-five dollars; 3 (3) Is of good moral character and temperate habits₇; 4 (4) Is not less than eighteen years of age, who is; 5 Is a graduate of a college of pharmacy recognized and approved by the board, and (5) 6 who has; Has had the necessary experience as determined by the board in the practice of 7 (6) 8 pharmacy under a regularly licensed pharmacist in a pharmacy where physicians' 9 prescriptions are compounded and who shall pass a satisfactory; and Has passed an examination prescribed by the State Board of Pharmacy, shall be 10 (7) 11 entitled to a certificate of registration as a licensed pharmacist board. The board shall have the authority to may allow credit for suitable military and 12 13 research activities in the field of pharmacy as part of the experience requirement.

14 Section 8. That § 36-11-19 be AMENDED:

36-11-19. The Board of Pharmacy board may in its discretion grant certificates of registration to such persons as shall furnish with their applications issue a license to practice pharmacy to individual who applies to the board and submits satisfactory proof that they have the individual has been registered licensed by examination in some other another state; provided that such the other state required a degree of competency at the time such person the individual was licensed at least equal to that required of licentiates in this state at that same time.

The State Board of Pharmacy, in order to be informed, board may, in determining the degree of fitness required by the several other states' boards of pharmacy for granting license and reciprocal registration_licensure, join with other states' boards of pharmacy. Every person_individual applying for registration_licensure pursuant to this section shall pay to the board upon an application a fee, not to exceed one hundred fifty dollars, set by the board by rule promulgated pursuant to chapter 1-26.

28 Section 9. That § 36-11-19.1 be AMENDED:

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36-11-19.1. Registered pharmacists <u>A pharmacist may:</u>

30 (1) Perform drug administration pursuant to a prescription drug order. The Board of
 31 Pharmacy shall establish standards for drug administration pursuant to chapter 1 32 26 with the approval of a committee composed of two persons appointed by the

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1		Board of Pharmacy, two persons appointed by the Board of Nursing and two
2		persons appointed by the Board of Medical and Osteopathic Examiners;
3	(2)	Perform drug reviews;
4	(3)	Perform or participate in scientific or clinical drug or drug-related research as an
5		investigator or in collaboration with other investigators;
6	(4)	Interpret and apply pharmacokinetic data and other pertinent laboratory data to
7		design safe and effective drug dosage regimens;
8	(5)	Participate in drug and drug device selection pursuant to a prescription drug order;
9	(6)	Initiate or modify drug therapy by protocol or other legal authority established and
10		approved within a licensed health care facility or by a practitioner authorized to
11		prescribe drugs; and
12	(7)	Provide information on prescription drugs, which may include advising, consulting,
13		and educating, as necessary or as required, patients, the public, and other health
14		care providers on the rational, safe and cost-effective use of drugs, including
15		therapeutic values, content, hazards and appropriate use.
16		The board shall establish standards for drug administration, in rules promulgated
17	pursuant to chapter 1-26, with the approval of a committee composed of two persons	
18	<u>appoir</u>	nted by the board, two persons appointed by the South Dakota Board of Nursing,
19	and tv	vo persons appointed by the State Board of Medical and Osteopathic Examiners.
20	Section 1	10. That § 36-11-19.5 be AMENDED:
21		36-11-19.5. Each nonresident pharmacy license expires on June thirtieth following
22	the da	te of -issue<u>issuance</u>. The board shall<u>mail an provide a renewal</u> application for license
23	renew	ral to each licensee before June first of each year. If the licensee does not submit a
24	renew	al application for renewal of the license, accompanied by the annual license the
25	renew	al fee is not made, before the expiration date, the existing license lapses on the
26	date o	f expiration. The board shall promulgate rules, pursuant to chapter 1-26, to establish

- the renewal fee, which may not exceed two hundred dollars. If the renewal application is
 submitted after the expiration of the license, the board must assess a fifty-dollar late fee
- 29 and may reinstate the license.
- 30 <u>If a majority of ownership of a licensed nonresident pharmacy changes, the new</u>
 31 <u>owners must, within thirty days after the ownership change:</u>
- 32 (1) Submit the renewal application, indicating the change of ownership; and
- 33 (2) Pay the renewal fee established by the board as provided in this section.

1 Section 11. That § 36-11-19.6 be AMENDED:

36-11-19.6. The board may deny, revoke, or suspend a nonresident pharmacy registration_license for conduct—which_that causes serious bodily injury or serious psychological injury to a resident of this state, if the board has referred the matter to the regulatory or licensing agency in the state in which the nonresident pharmacy is located and the regulatory or licensing agency fails to initiate an investigation within forty-five days after the referral.

8 Any action taken to deny, revoke, or suspend a nonresident pharmacy-registration
9 license is a contested case proceeding pursuant to chapter 1-26.

10 Section 12. That § 36-11-20 be AMENDED:

- 36-11-20. The Board of Pharmacy board may, in compliance with chapter 1-26,
 suspend, revoke, or refuse to grant issue or renew a license or certificate of registration
 to practice pharmacy to any person who:
- 14 (1) Is guilty of a felony or a misdemeanor involving moral turpitude, or who is;
- <u>(2)</u> Is addicted to the use of alcoholic liquors or narcotic drugs to such an extent as to
 render-<u>him_the person</u> unfit to practice pharmacy with reasonable skill and safety;
 and the board may, in compliance with chapter 1-26, revoke a license for like
 cause, or any license which has been procured
- <u>Procured a license</u> by fraud or by false representation. Any license or registration,
 or renewal thereof, obtained through fraud or by any fraudulent or false
 representations shall be void. The board may suspend, revoke or refuse to grant a
 license or certificate of registration to any person;
- 23 (4) Is permitting or engaging in the unauthorized sale of legend or controlled drugs or
 24 substances or who the; or
- 25 (5) The board finds to be in violation of any law, rule, or regulation governing
 26 pharmacists.

27 Section 13. That § 36-11-23 be AMENDED:

36-11-23. Each To renew a license to practice pharmacy, a pharmacist shall must
 annually by October first, on or before September thirtieth of each year, submit a renewal
 application and pay to the board a registry renewal fee to be fixed set by the board in
 compliance rules promulgated in accordance with chapter 1-26, not to exceed one hundred
 fifty dollars. Upon application and payment of the fee by a pharmacist, the Board of

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- 1 Pharmacy, the board shall renew the pharmacist's certificate of registration. Any license.
- 2 If a pharmacist who fails to apply and pay the renewal fee by the due date is subject to
- 3 suspension of certificate by the board in compliance with chapter 1-26. Any suspended
- 4 certificate may be reinstated, the license expires.
 - The board may reinstate an expired license if the individual:
- 6 (1) Applies for reinstatement; and
- 7 (2) Pays all delinquent fees have been paid, plus a penalty of twenty- five dollars, and
 8 the Board of Pharmacy has approved the application for reinstatement, plus a fifty 9 dollar late fee.
- 10 Section 14. That § 36-11-25 be AMENDED:

11 36-11-25. Pharmacy The board may issue a pharmacy intern-certificates may be 12 issued by the Board of Pharmacy certificate to persons an individual who are is gaining 13 experience as a qualification for licensure as a registered pharmacist. Any pharmacy intern 14 granted issued an intern certificate shall perform his the internship pursuant to regulations 15 which shall be rules promulgated by the Board of Pharmacy board in accordance with chapter 1-26. Nothing in this section shall may be construed as giving such a pharmacy 16 17 intern authority to fill any prescription, except under the supervision and in the presence 18 of the registered pharmacist.

- 19 Section 15. That § 36-11-26 be AMENDED:
- 36-11-26. If the Board of Pharmacy board is satisfied that any person holding a
 certificate of registration pharmacist is for any reason incompetent or disqualified to
 perform the duties of a registered pharmacist pursuant to § 36-11-20 or as contemplated
 by the provisions of this chapter, it may, in compliance with § 36-11-28 chapter 1-26:
- 24 (1) Issue a reprimand to the registrant pharmacist;
- 25 (2) Place the registrant pharmacist on probation and supervision;
- 26 (3) Suspend the registrant's certificate pharmacist's license until he the pharmacist
 27 completes a course of therapy, treatment, training, or any combination thereof;
- 28 (4) Suspend the registrant's certificate pharmacist's license for a fixed period; and
- 29 (5) Revoke the registrant's certificate pharmacist's license.
- 30 <u>An individual may appeal a decision of the board as provided in chapter 1-26.</u>

31 Section 16. That § 36-11-30 be AMENDED:

1	36-11-30. No <u>A person may not open or operate a p</u> harmacy shall open or be kept
2	open for transaction of business until it has been registered and a permit issued unless
3	the pharmacy is licensed by the State Board of Pharmacy board.
4	A violation of this section is a Class 2 misdemeanor. Each day of violation is a
5	separate offense.
6	Section 17. That § 36-11-31 be AMENDED:
7	36-11-31. No Only a person, copartnership or corporation that has a pharmacy
8	license issued by the board may carry:
9	(1) Carry on, conduct, or transact business under a name which that contains as a part
10	thereof the term or words "drug department," "drugstore," -or "pharmacy," or any
11	term implying the operation of a pharmacy or drugstore, or in any manner by
12	advertisement, circular, poster, sign or otherwise describe; and
13	(2) Advertise, describe, or refer to a place of business, in any manner, by the terms
14	"drugstore" or "pharmacy," or any other term or words-which may be applied to
15	establishments where drugs, medicines, and poisons are usually dispensed or
16	distributed, unless the place of business so conducted is a pharmacy duly
17	authorized and registered by the State Board of Pharmacy implying the operation
18	of a pharmacy.
19	A violation of this section is a Class 2 misdemeanor.
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20	Section 18. That § 36-11-32 be AMENDED:
21	36-11-32. Upon The board shall issue a pharmacy license to a pharmacist in good
22	standing, if the pharmacist:
23	(1) Submits a form prescribed by the State Board of Pharmacy board; and the payment
24	of
25	(2) Pays a fee, not to exceed two hundred dollars, set by the Board of Pharmacy board
26	in <u>rules promulgated in</u> accordance with chapter 1-26 , the State Board of Pharmacy
27	shall issue to pharmacists in good standing, registered under the laws of this state,
28	a permit to conduct a pharmacy.
29	Section 19. That § 36-11-33 be AMENDED:
30	36-11-33. The Board of Pharmacy board may issue to pharmacists a pharmacist
31	in good standing a permit license to conduct operate a part-time limited or conditional

in good standing a permit license to conduct operate a part-time, limited, or conditional 31

1 pharmacy in hospitals a hospital, nursing homes facility, or related facilities facility, 2 provided that the pharmacy services are limited to patients inpatients or residents of the 3 facility. 4 A permit to conduct a pharmacy, the The board may issue a license under this 5 section if: 6 (1)The pharmacist submits a form prescribed by the board and pays a fee, not to 7 exceed two hundred dollars, set by the board in rules promulgated in accordance 8 with chapter 1-26; and The merchandise and fixtures of which the pharmacy are owned by a person, firm, 9 (2) or corporation other than a registered the pharmacist, upon said registered 10 pharmacist making application for a permit hereunder, may be issued and granted 11 12 to the said registered pharmacist, on compliance applying for the license. 13 The pharmacist must comply with the provisions of this chapter, and with minimum 14 standards as established by the board in rules promulgated pursuant to chapter 1-26. 15 Section 20. That § 36-11-34 be AMENDED: 16 36-11-34. No permit to conduct The board may not issue a pharmacy shall be 17 issued license to any pharmacist applicant unless such pharmacist: 18 (1)The applicant is the owner, or part owner, of the merchandise and fixtures of the 19 place of business for which such the pharmacy registration license is applied for₇ 20 or unless; 21 $(2)_{-}$ <u>The application is made jointly with a registered pharmacist owner,</u> or unless the 22 The nonpharmacist owner of the merchandise and fixtures of the place of business (3) 23 for which the pharmacy-registration license is applied for, has-made submitted an 24 affidavit on a form prescribed by the state board of pharmacy delegating complete 25 responsibility for the pharmaceutical services in said place of business to the pharmacist applicant. 26 27 Section 21. That § 36-11-35 be AMENDED: 28 **36-11-35.** Each permit for a pharmacy shall constitute and signify a legal 29 registration for the pharmacy to which it applies, and shall expire pharmacy license expires 30 on-the last day of June_thirtieth following the date of issue. To renew a pharmacy license, 31 the pharmacist must submit a renewal application on or before June thirtieth on a form prescribed by the board, and pay the renewal fee set by the board in rules promulgated 32 33 in accordance with chapter 1-26, but not exceeding two hundred dollars. If the renewal

1 <u>application and fee is submitted after the expiration of the license, the board must assess</u>

- 2 <u>a fifty-dollar late fee and may reinstate the license.</u>
- 3 If a majority ownership of the pharmacy changes, the new owners must, within
 4 thirty days after ownership change:
- 5 (1) Submit the renewal application, indicating the change of ownership; and
- 6 (2) Pay the renewal fee established by the board as provided in this section.

7 Section 22. That § 36-11-36 be AMENDED:

36-11-36. Each permit for a pharmacy, together with a certificate naming the
 pharmacist actively conducting said pharmacy, license issued by the State Board of
 Pharmacy, which shall be a part of said permit, shall board must be exposed posted in a
 conspicuous place in the pharmacy to which it applies that is viewable by the public.

12 Section 23. That § 36-11-37 be AMENDED:

13 **36-11-37.** Each permit for a A pharmacy license may be transferred to another pharmacist in good standing and registered under the laws of this state without the 14 15 payment of an additional fee;, provided an application for the transfer of said permit the 16 license is made upon a form prescribed by the State Board of Pharmacy board and upon 17 payment of a fifty dollar fee. The application for transfer must be filed with the secretary thereof board not less more than ten days before after the transfer of such active 18 19 management is made. If the application for transfer is received by the board after ten 20 days, the pharmacy license is void, and the pharmacist must reapply for the license.

21 Section 24. That § 36-11-38 be AMENDED:

36-11-38. In the event of the death of the pharmacist <u>permittee in active</u>
 <u>management</u>, the pharmacy<u>permit_license</u> issued to the deceased under this chapter
 shall, within one hundred twenty days after the <u>date of</u> death <u>of such permittee or on June</u>
 <u>thirtieth, whichever is sooner</u>, become null and void, unless <u>transfer thereof</u>, <u>the license</u>
 <u>is transferred</u> as provided in § 36-11-37, <u>shall have been made within the said one</u>
 <u>hundred twenty day period</u>.

28 Section 25. That § 36-11-39 be AMENDED:

36-11-39. The change of location of any pharmacy for which a permit license has
 been issued from one municipality to another within this state, any change in the

1 ownership of such pharmacy, or the cessation of business by such the pharmacy shall,

- 2 <u>must</u> be reported to the <u>State Board of Pharmacy board</u> within ten days from <u>such the</u>
- 3 occurrence on forms prescribed by the State Board of Pharmacy board.

4 Section 26. That § 36-11-41 be AMENDED:

- 5 **36-11-41.** No permit may be issued under 36-11-32 unless<u>A pharmacy licensed</u>
 6 by the board must:
- 7 (1) The pharmacy is <u>Be</u> equipped with the pharmaceutical instruments and utensils
 8 prescribed by the <u>State Board of Pharmacy</u>, and <u>shall possess</u> <u>board in rules</u>
 9 promulgated in accordance with chapter 1-26;
- <u>(2) Possess</u> a stock of pharmaceuticals adequate to serve the needs of the community
 in which the pharmacy is located; and
- (2)(3) The pharmacy has <u>Have</u> on file at all times the publications and supplements of
 formularies and drug information prescribed by the board, by rules promulgated
 pursuant to chapter 1-26; and
- 15 (4) Be maintained and operated in a clean and sanitary condition, free from unhealth,
 16 foreign, or injurious contamination.

17 Section 27. That § 36-11-43 be AMENDED:

36-11-43. The Board of Pharmacy board may, in the manner provided by rules 18 19 promulgated in accordance with chapter 1-26, adopt a code of professional ethics for 20 pharmacists in this state in the practice of their profession. In adopting such code, or any 21 amendments thereafter, the. The board will shall consider the recommendations of the 22 South Dakota Pharmacists Association and the vote of its members, provided however, 23 that any such in adopting the code or changes made thereto. The code so adopted shall 24 at no time may not contain any provision that would in any way restrain, prohibit, or 25 attempt to regulate the rights of any pharmacist to be employed in any a licensed 26 pharmacy holding a valid pharmacy permit. Violation of the code of professional ethics 27 shall may not be the basis for criminal prosecution unless otherwise declared unlawful.

28 Section 28. That § 36-11-44 be AMENDED:

36-11-44. Any registered pharmacist who permits the compounding or dispensing
 of prescriptions or the vending of drugs or poisons in his store or in the pharmacist's place
 of business, except under the personal supervision of a registered pharmacist, or any

1 pharmacist who, while continuing in business, makes any false representations to procure

- 2 registration for himself a license for the pharmacist or any other person, is guilty of a
- 3 Class 2 misdemeanor.

4 Section 29. That § 36-11-48 be AMENDED:

5 36-11-48. The State Board of Pharmacy board may suspend or revoke, in 6 accordance with chapter 1-26, any permit obtained pharmacy license issued under this 7 chapter on the following grounds: 8 (1)<u>The license was obtained</u> by false representations made in the application therefor₇ 9 or when the; 10 The pharmacy for which the permit shall be license was issued is was kept open (2) 11 for the transaction of business without a registered pharmacist in charge thereof, 12 or upon conviction; 13 (3) Conviction of a violation of any law of this state or of the United States pertaining 14 to the drug business or for the aiding or abetting in the violation of any such the 15 law; The active management of the pharmacy was changed without the transfer, as 16 (4) provided in § 36-11-37, of the license; 17 18 (5) The location of the pharmacy was changed without the change being reported as 19 provided in \S 36-11-39: 20 (6) The pharmacy was kept open for the transaction of business after the pharmacist 21 ceased to be in active management of the pharmacy; or 22 The minimum requirements of this chapter and the board are no longer met. (7)23 A pharmacy license may not be suspended or revoked except by a vote of three or 24 more members of the board.

25 Section 30. That § 36-11-67 be AMENDED:

36-11-67. Pharmacists licensed under this chapter <u>A pharmacist</u> or <u>physicians</u> physician licensed under chapter 36-4 who <u>participate on participates in</u> a drug utilization review program as defined in § 36-11-2 are is not individually or jointly <u>not</u> subject to, and <u>are is</u> immune from, claim, suit, liability, damages, or any other recourse, civil or criminal, arising from any act or proceeding, decision, or determination undertaken, performed, or reached in good faith and without malice when acting individually or jointly in carrying out the responsibilities, authority, duties, powers, and privileges of the

1 program conferred upon them under any provisions of law or rule, good faith being 2 presumed until proven otherwise, with malice required to be shown by the complainant. 3 For the purposes of this section, a "drug utilization review program" is a program 4 operated solely or partially as a professional standards review organization whose purpose 5 is to: 6 (1) Educate pharmacists and practitioners on: 7 Severe adverse reactions to drugs; (a) 8 (b) Therapeutic appropriateness; 9 (c) Overutilization; (d) Underutilization; 10 11 (e) Appropriate use of generic products; 12 (f) Therapeutic duplication; 13 (q) Drug-disease contraindications; 14 Drug-drug interactions; (h) 15 Incorrect drug dosage or duration of drug treatment; (i) 16 (j) Drug-allergy interactions; and 17 Clinical abuse or misuse; and (k) Identify and reduce the frequency of patterns of potential and actual fraud, abuse, 18 (2) gross overuse, inappropriate care, or medically unnecessary care associated with 19 20 specific drugs or groups of drugs among practitioners, pharmacists, and patients. 21 Section 31. That § 36-11-72 be AMENDED: 22 **36-11-72.** The board shall promulgate rules pursuant to chapter 1-26 to provide 23 for the regulation of telepharmacy in the this state. The rules shall include must provide 24 for: 25 (1)License and renewal application requirements, including-establishment: 26 (a) Establishment of an annual initial license fee and a renewal fee, each not to 27 exceed two hundred fifty dollars; 28 Procedures for the reinstatement of an expired license; and (b) 29 (c) Establishment of a late fee for reinstating an expired license, not to exceed 30 fifty dollars; 31 Minimum structural, security, and equipment requirements for the remote (2) 32 pharmacv: 33 (3) Minimum staffing requirements for the central pharmacy and remote pharmacy; 34 (4) Record keeping requirements for the central pharmacy and remote pharmacy;

- (5) Establishment of policies Policies and procedures for the daily operation of the
 remote pharmacy; and
- 3 (6) Use of automated dispensing machines.

4 Section 32. That a NEW SECTION be added to chapter 36-11:

- 5 If the majority of ownership of a remote pharmacy changes, the new owners must,
 6 within thirty days after the ownership change:
- 7 (1) Submit the renewal application prescribed by the board, as provided in § 36-11 8 72, indicating the change of ownership; and
- 9 (2) Pay the renewal fee established by the board, as provided in § 36-11-72.

10 Section 33. That § 36-11A-8 be AMENDED:

- **36-11A-8.** An applicant for licensure as a To apply for a wholesale or other drug distributor shall apply annually to the board license, a person must submit an application on a form provided by the board. The application shall be accompanied by a and pay an annual license fee set by the board. The fee may not exceed two, not to exceed five hundred fifty dollars.
- All financial statements or related information submitted by applicants <u>shall must</u>
 be treated as confidential materials.

18 Section 34. That § 36-11A-13 be AMENDED:

- 19 36-11A-13. Each wholesale drug distributor license expires on December thirty-20 first following the date of issue issuance. The board shall provide an application for license 21 renewal to each licensee before December first of each year. To renew a license, the 22 licensee shall submit the renewal application and pay the annual license fee set by the 23 board as provided in § 36-11A-8. If application for renewal of the license accompanied by 24 the annual license fee is not made before the expiration date, the existing license lapses 25 on the date of expiration. If the board receives a renewal application and fee for an expired 26 license, the board must assess a fifty-dollar late fee and may reinstate the license.
- 27 If the majority of ownership of a licensed facility changes, the new owners must,
 28 within thirty days after the ownership change:
- 29 (1) Submit a renewal application, indicating the change of ownership; and
- 30 (2) Pay a fee equal to the annual license fee.

31 Section 35. That § 36-11-3 be REPEALED.

1 Those registered pharmacists of this state electing to participate shall constitute an association under the name and title of the South Dakota Pharmacists Association. The 2 3 purpose of the association is to serve as the state professional society of pharmacists 4 which represents the profession of pharmacy, enhances the public's awareness of 5 pharmacy, and serves the best interest of public health and pharmacy. The South Dakota 6 Pharmacists Association shall be conducted as a nonprofit corporation pursuant to the 7 terms of its articles of incorporation. The members of the association who have secured a 8 current annual certificate of registration to practice pharmacy in this state and who have 9 elected to participate in the association are entitled to all of the rights and privileges of 10 the association and may vote, serve as an officer or director of the association, and participate in all of the meetings of the association. The association shall hold an annual 11 12 meeting at such time and place as it determines.

13 Section 36. That § 36-11-6 be REPEALED.

The board may, upon receipt, pay to the South Dakota Pharmacists Association 14 15 eighty percent of all fees the board receives for renewals of certificates of registration as a pharmacist. The association shall use the funds for the following association activities to 16 17 benefit the public and the profession: continuing education, matters related to registration 18 standards for pharmacists, professional service standards, and general operating 19 expenses related to the activities enumerated in this section. The association shall also 20 use funds received to pay any legislated assessment to support a diversion program for chemically impaired pharmacists. Expenditures of funds shall be approved by the 21 22 president and treasurer of the association. The association shall annually file in the office 23 of the board an itemized statement of the receipts of the association and disbursements 24 from the receipts.

25 Section 37. That § 36-11-17 be REPEALED.

Every person initially applying for a certificate of registration with the Board of Pharmacy as a registered pharmacist shall pay to the board with the application a fee, not to exceed thirty-five dollars, set by the board by rule promulgated pursuant to chapter 1-29 26.

30 Section 38. That § 36-11-18 be REPEALED.

1It shall be the duty of the Board of Pharmacy to examine all applications for2registration submitted in due form as provided in the rules and regulations of the board3and to grant certificates of registration to such persons as may be entitled to the same

4 under the provisions of this chapter.

5 Section 39. That § 36-11-22 be REPEALED.

The Board of Pharmacy shall keep a record of registration in which shall be entered
 the names and places of business of all persons registered under this chapter which
 records shall also specify such facts as such persons shall claim to justify their registration.

9 Section 40. That § 36-11-28 be REPEALED.

A certificate of registration as a pharmacist shall not be revoked or suspended
 except after hearing before the Board of Pharmacy at which a majority of its members are
 present and in compliance with chapter 1-26.

13 Section 41. That § 36-11-29 be REPEALED.

An appeal from the decision of the Board of Pharmacy may be taken as provided
 by chapter 1-26.

16 Section 42. That § 36-11-40 be REPEALED.

Any permit issued under the provisions of § 36-11-32 shall be void if the active management of any pharmacy is changed without the transfer, as provided in § 36-11-37, of the permit therefor, or if the location of said pharmacy is changed without the same being reported as provided in § 36-11-39, or if the pharmacy is kept open for business after the permittee has ceased to be in active management of said pharmacy, and whenever the minimum requirements of this chapter and the Board of Pharmacy are no longer met.

24 Section 43. That § 36-11-42 be REPEALED.

Any permit issued under the provisions of § 36-11-32 shall be void and subject to
 cancellation by the State Board of Pharmacy, unless such pharmacy is maintained and
 operated in a clean and sanitary condition, free from unhealthful, foreign, or injurious
 contamination.

1 Section 44. That § 36-11-49 be REPEALED.

Before any permit for a pharmacy shall be revoked chapter 1-26 shall be complied
 with. Two members of the board shall constitute a quorum and no permit shall be revoked
 except by a vote of two or more members of the State Board of Pharmacy.

5 Section 45. That § 36-11A-4.2 be REPEALED.

- No outsourcing facility engaged in compounding of nonpatient specific sterile and
 nonsterile drugs may become licensed by the board without first obtaining a registration
 and inspection by the United States Food and Drug Administration, and paying the license
 fee set by the board in rules promulgated pursuant to chapter 1-26. The fee may not
 exceed two hundred dollars.
- Section 46. No later than September 30, 2025, the Board of Pharmacy shall, pursuant to chapter 1-26, provide for and file with the secretary of state, the amendment of ARSD 20:67:02:01, as set forth below:
- 14 **20:67:02:01. Application and fee.** A wholesale or other distributor must 15 apply each year to the board, electronically or on a form supplied by the secretary of the 16 board, for a license to engage in the distribution of prescription drugs. Each application 17 shall must be accompanied by a license fee of \$200 five hundred dollars.
- 18
 Source: 18 SDR 95, effective November 25, 1991; 24 SDR 160, effective May

 19
 26, 1998; 45 SDR 86, effective December 24, 2018.
- 20 **General Authority:** SDCL 36-11A-14(1),(6).
- 21 Law Implemented: SDCL 36-11A-7, 36-11A-8.