2025 South Dakota Legislature

House Bill 1016

ENROLLED

AN ACT

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

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

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

13-33A-4. Any school may acquire and maintain a stock of epinephrine auto-injectors 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 chapter 36-11.

Section 2. That § 36-11-2 be AMENDED:

36-11-2. Terms used in this chapter mean:

(1) "Biological product," as defined in 42 U.S.C. § 262(i), (January 1, 2018);

(2) "Board," the State Board of Pharmacy;

(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;

(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;

(5) "Delivery," the actual, constructive, or attempted transfer of a drug or drug device from one person to another, whether or not for a consideration;

(6) "Dispensing," the preparation and delivery of a drug to a patient or a patient's agent pursuant to a prescription drug order in a suitable container with appropriate

labeling for subsequent administration to or use by a patient. The term includes preparation of labels for drug devices if the labeling is related to the dosage and administration of drugs;

(7) "Distributing," the delivery of a drug or drug device other than by administration or dispensing;

(8) "Drug administration," the direct application of a drug or drug device by injection, inhalation, ingestion, or any other means to the body of a patient or research subject;

(9) "Drug device," equipment, process, biotechnological entity, diagnostic agent, or other product used in combination with a drug to provide effective management of medication regimens;

(10) "Equivalent drug product," a drug product, other than a biological product, that is considered to be therapeutically equivalent to other pharmaceutically equivalent products as determined by the edition of Approved Drug Products with Therapeutic Equivalence Evaluations adopted by the board through rules promulgated pursuant to chapter 1-26;

(11) "Interchangeable biological product," a biological product that the United States Food and Drug Administration either has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. § 262(k)(4), (January 1, 2018), or has determined is therapeutically equivalent, as set forth in the edition of Approved Drug Products with Therapeutic Equivalence Evaluations as adopted by the board through rules promulgated pursuant to chapter 1-26;

(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;

(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;

(14) "Nonprescription drugs," drugs that are labeled for use by the general public in accordance with 21 U.S.C. § 352 (January 1, 2025), and may be sold without a prescription drug order in accordance with 21 U.S.C. § 353 (January 1, 2025). The term does not include drugs that are required by federal law to bear the statement "Caution: federal law prohibits dispensing without prescription," drugs intended for human use by hypodermic injection, or animal remedies regulated by chapter 39-18;

(15) "Patient counseling," oral communication by the pharmacist of information to the patient or caregiver to improve therapy by ensuring proper use of drugs and drug devices;

(16) "Pharmaceutical care," provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to curing or preventing a disease, eliminating or reducing a patient's symptoms, or arresting or slowing a disease process;

(17) "Pharmacist," a person licensed by the board to engage in the practice of pharmacy;

(18) "Pharmacy," any place of business within or outside this state where drugs are dispensed and pharmaceutical care is provided to residents of this state;

(19) "Practitioner," a person licensed, registered, or otherwise authorized by the jurisdiction in which the person is practicing to prescribe drugs in the course of professional practice;

(20) "Prescription drug order," a written or oral order of a practitioner for a drug or drug device for a specific patient;

(21) "Proper name," the nonproprietary name for a biological product designated by the United States Food and Drug Administration license for use upon each package of the product; and

(22) "Registered pharmacy technician," a person registered by the board who is employed by a pharmacy to assist pharmacists in the practice of pharmacy by performing specific tasks delegated by and under the immediate personal supervision and control of a pharmacist, as permitted by the board.

Section 3. That § 36-11-2.1 be AMENDED:

36-11-2.1. For the purpose of this chapter, "drugs" are:

(1) Articles recognized in the official United States Pharmacopoeia or the official National Formulary, as adopted by the board through rules promulgated pursuant to chapter 1-26, or recognized in the official Homeopathic Pharmacopoeia of the United States as in effect on January 1, 1993;

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(3) Articles, other than food, intended to affect the structure or any functions of the human body; and

(4) Articles intended for use as a component of any articles specified in this section.

The term "drugs" excludes medical devices.

For the purposes of this section, "medical device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any 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 in humans or animals, or is intended to affect the structure or any function of the body of humans or animals, that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or animals and that is not dependent upon being metabolized for achievement of any of its principal intended purposes.

Section 4. That § 36-11-5 be AMENDED:

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

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

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

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

36-11-15. Any person, other than a 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 pharmacist, is guilty of a Class 2 misdemeanor.

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

36-11-16. The board shall issue a license to practice pharmacy to an individual who:

(1) Submits an application prescribed by the board;

(2) Submits an application fee set by the board through rules promulgated in accordance with chapter 1-26, but not exceeding thirty-five dollars;

(3) Is of good moral character and temperate habits;

(4) Is not less than eighteen years of age;

(5) Is a graduate of a college of pharmacy recognized and approved by the board;

(6) Has had the necessary experience as determined by the board in the practice of pharmacy under a regularly licensed pharmacist in a pharmacy where physicians' prescriptions are compounded; and

(7) Has passed an examination prescribed by the board.

The board may allow credit for suitable military and research activities in the field of pharmacy as part of the experience requirement.

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

36-11-19. The board may issue a license to practice pharmacy to individual who applies to the board and submits satisfactory proof that the individual has been licensed by examination in another state, provided that the other state required a degree of competency at the time the individual was licensed at least equal to that required in this state at that same time.

The board may, in determining the degree of fitness required by other states' boards of pharmacy for granting licensure, join with other states' boards of pharmacy. Every individual applying for licensure pursuant to this section shall pay to the board an application fee, not to exceed one hundred fifty dollars, set by the board by rule promulgated pursuant to chapter 1-26.

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

36-11-19.1. A pharmacist may:

(1) Perform drug administration pursuant to a prescription drug order;

(2) Perform drug reviews;

(3) Perform or participate in scientific or clinical drug or drug-related research as an investigator or in collaboration with other investigators;

(4) Interpret and apply pharmacokinetic data and other pertinent laboratory data to design safe and effective drug dosage regimens;

(5) Participate in drug and drug device selection pursuant to a prescription drug order;

(6) Initiate or modify drug therapy by protocol or other legal authority established and approved within a licensed health care facility or by a practitioner authorized to prescribe drugs; and

(7) Provide information on prescription drugs, which may include advising, consulting, and educating, as necessary or as required, patients, the public, and other health

care providers on the rational, safe and cost-effective use of drugs, including therapeutic values, content, hazards and appropriate use.

The board shall establish standards for drug administration, in rules promulgated pursuant to chapter 1-26, with the approval of a committee composed of two persons appointed by the board, two persons appointed by the South Dakota Board of Nursing, and two persons appointed by the State Board of Medical and Osteopathic Examiners.

Section 10. That § 36-11-19.5 be AMENDED:

36-11-19.5. Each nonresident pharmacy license expires on June thirtieth following the date of issuance. The board shall provide a renewal application to each licensee before June first of each year. If the licensee does not submit a renewal application, accompanied by the renewal fee, before the expiration date, the license lapses on the date of 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 and may reinstate the license.

If a majority of ownership of a licensed nonresident pharmacy changes, the new owners must, within thirty days after the ownership change:

(1) Submit the renewal application, indicating the change of ownership; and

(2) Pay the renewal fee established by the board as provided in this section.

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

36-11-19.6. The board may deny, revoke, or suspend a nonresident pharmacy license for conduct 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.

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

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

36-11-20. The board may, in compliance with chapter 1-26, suspend, revoke, or refuse to issue or renew a license to practice pharmacy to any person who:

(1) Is guilty of a felony or a misdemeanor involving moral turpitude;

(2) Is addicted to the use of alcoholic liquors or narcotic drugs to such an extent as to render the person unfit to practice pharmacy with reasonable skill and safety;

(3) Procured a license by fraud or by false representation;

(4) Is permitting or engaging in the unauthorized sale of legend or controlled drugs or substances; or

(5) The board finds to be in violation of any law, rule, or regulation governing pharmacists.

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

36-11-23. To renew a license to practice pharmacy, a pharmacist must, on or before September thirtieth of each year, submit a renewal application and pay to the board a renewal fee set by the board in rules promulgated in accordance with chapter 1-26, not to exceed one hundred fifty dollars. Upon application and payment of the fee, the board shall renew the license. If a pharmacist fails to apply and pay the renewal fee, the license expires.

The board may reinstate an expired license if the individual:

(1) Applies for reinstatement; and

(2) Pays all delinquent fees, plus a fifty-dollar late fee.

Section 14. That § 36-11-25 be AMENDED:

36-11-25. The board may issue a pharmacy intern certificate to an individual who is gaining experience as a qualification for licensure as a pharmacist. Any pharmacy intern issued an intern certificate shall perform the internship pursuant to rules promulgated by the board in accordance with chapter 1-26. Nothing in this section may be construed as giving a pharmacy intern authority to fill any prescription, except under the supervision and in the presence of the pharmacist.

Section 15. That § 36-11-26 be AMENDED:

36-11-26. If the board is satisfied that any pharmacist is incompetent or disqualified to perform the duties of a pharmacist pursuant to § 36-11-20 or as contemplated by the provisions of this chapter, it may, in compliance with chapter 1-26:

(1) Issue a reprimand to the pharmacist;

(2) Place the pharmacist on probation and supervision;

(3) Suspend the pharmacist's license until the pharmacist completes a course of therapy, treatment, training, or any combination thereof;

(4) Suspend the pharmacist's license for a fixed period; and

(5) Revoke the pharmacist's license.

An individual may appeal a decision of the board as provided in chapter 1-26.

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

36-11-30. A person may not open or operate a pharmacy unless the pharmacy is licensed by the board.

A violation of this section is a Class 2 misdemeanor. Each day of violation is a separate offense.

Section 17. That § 36-11-31 be AMENDED:

36-11-31. Only a person that has a pharmacy license issued by the board may:

(1) Carry on, conduct, or transact business under a name that contains the term or words "drugstore," "pharmacy," or any term implying the operation of a pharmacy; and

(2) Advertise, describe, or refer to a place of business, in any manner, by the terms "drugstore" or "pharmacy," or any other term or words implying the operation of a pharmacy.

A violation of this section is a Class 2 misdemeanor.

Section 18. That § 36-11-32 be AMENDED:

36-11-32. The board shall issue a pharmacy license to a pharmacist in good standing, if the pharmacist:

(1) Submits a form prescribed by the board; and

(2) Pays a fee, not to exceed two hundred dollars, set by the board in rules promulgated in accordance with chapter 1-26.

Section 19. That § 36-11-33 be AMENDED:

36-11-33. The board may issue to a pharmacist in good standing a license to operate a part-time pharmacy in a hospital, nursing facility, or related facility, provided that the pharmacy services are limited to inpatients or residents of the facility.

The board may issue a license under this section if:

(1) The pharmacist submits a form prescribed by the board and pays a fee, not to exceed two hundred dollars, set by the board in rules promulgated in accordance with chapter 1-26; and

(2) The merchandise and fixtures of the pharmacy are owned by a person other than the pharmacist applying for the license.

The pharmacist must comply with the provisions of this chapter and with minimum standards as established by the board in rules promulgated pursuant to chapter 1-26.

Section 20. That § 36-11-34 be AMENDED:

36-11-34. The board may not issue a pharmacy license to any pharmacist applicant unless:

(1) The applicant is the owner, or part owner, of the merchandise and fixtures of the place of business for which the pharmacy license is applied for;

(2) The application is made jointly with a pharmacist owner; or

(3) The nonpharmacist owner of the merchandise and fixtures of the place of business for which the pharmacy license is applied for, has submitted an affidavit on a form prescribed by the board delegating complete responsibility for the pharmaceutical services in said place of business to the pharmacist applicant.

Section 21. That § 36-11-35 be AMENDED:

36-11-35. Each pharmacy license expires on June thirtieth following the date of issue. To renew a pharmacy license, 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 in accordance with chapter 1-26, but not exceeding two hundred dollars. If the renewal application and fee is submitted after the expiration of the license, the board must assess a fifty-dollar late fee and may reinstate the license.

If a majority ownership of the pharmacy changes, the new owners must, within thirty days after ownership change:

(1) Submit the renewal application, indicating the change of ownership; and

(2) Pay the renewal fee established by the board as provided in this section.

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

36-11-36. Each pharmacy license issued by the board must be posted in a place in the pharmacy that is viewable by the public.

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

36-11-37. A pharmacy license may be transferred to another pharmacist, provided an application for the transfer of the license is made upon a form prescribed by the board and upon payment of a fifty dollar fee. The application for transfer must be filed with the board not more than ten days after the transfer of active management is made. If the application for transfer is received by the board after ten days, the pharmacy license is void, and the pharmacist must reapply for the license.

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

36-11-38. In the event of the death of the pharmacist in active management, the pharmacy license issued to the deceased under this chapter shall, within one hundred twenty days after the date of death or on June thirtieth, whichever is sooner, become null and void, unless the license is transferred as provided in § 36-11-37,.

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

36-11-39. The change of location of any pharmacy for which a license has been issued from one municipality to another within this state, or the cessation of business by the pharmacy, must be reported to the board within ten days from the occurrence on forms prescribed by the board.

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

36-11-41. A pharmacy licensed by the board must:

(1) Be equipped with the pharmaceutical instruments and utensils prescribed by the board in rules promulgated in accordance with chapter 1-26;

(2) Possess a stock of pharmaceuticals adequate to serve the needs of the community in which the pharmacy is located;

(3) Have 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

(4) Be maintained and operated in a clean and sanitary condition, free from unhealth, foreign, or injurious contamination.

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

36-11-43. The board may, in rules promulgated in accordance with chapter 1-26, adopt a code of professional ethics for pharmacists in this state. The board shall consider the recommendations of the South Dakota Pharmacists Association in adopting the code or changes made thereto. The code may not contain any provision that would in any way restrain, prohibit, or attempt to regulate the rights of any pharmacist employed in a licensed pharmacy. Violation of the code of professional ethics may not be the basis for criminal prosecution unless otherwise declared unlawful.

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

36-11-44. Any pharmacist who permits the compounding or dispensing of prescriptions or the vending of drugs in the pharmacist's place of business, except under the personal supervision of a pharmacist, or any pharmacist who, while continuing in business, makes any false representations to procure a license for the pharmacist or any other person, is guilty of a Class 2 misdemeanor.

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

36-11-48. The board may suspend or revoke, in accordance with chapter 1-26, any pharmacy license issued under this chapter on the following grounds:

(1) The license was obtained by false representations made in the application therefor;

(2) The pharmacy for which the license was issued was kept open for the transaction of business without a pharmacist in charge thereof;

(3) Conviction of a violation of any law of this state or of the United States pertaining to the drug business or for the aiding or abetting in the violation of the law;

(4) The active management of the pharmacy was changed without the transfer, as provided in § 36-11-37, of the license;

(5) The location of the pharmacy was changed without the change being reported as provided in § 36-11-39;

(6) The pharmacy was kept open for the transaction of business after the pharmacist ceased to be in active management of the pharmacy; or

(7) The minimum requirements of this chapter and the board are no longer met.

A pharmacy license may not be suspended or revoked except by a vote of three or more members of the board.

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

36-11-67. A pharmacist or physician licensed under chapter 36-4 who participates in a drug utilization review program is not individually or jointly subject to, and is 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 program conferred upon them under any provisions of law or rule, good faith being presumed until proven otherwise, with malice required to be shown by the complainant.

For the purposes of this section, a "drug utilization review program" is a program operated solely or partially as a professional standards review organization whose purpose is to:

(1) Educate pharmacists and practitioners on:
   (a) Severe adverse reactions to drugs;
   (b) Therapeutic appropriateness;
   (c) Overutilization;
   (d) Underutilization;
   (e) Appropriate use of generic products;
   (f) Therapeutic duplication;
   (g) Drug-disease contraindications;
   (h) Drug-drug interactions;
   (i) Incorrect drug dosage or duration of drug treatment;
   (j) Drug-allergy interactions; and
   (k) Clinical abuse or misuse; and

(2) Identify and reduce the frequency of patterns of potential and actual fraud, abuse, gross overuse, inappropriate care, or medically unnecessary care associated with specific drugs or groups of drugs among practitioners, pharmacists, and patients.

Section 31. That § 36-11-72 be AMENDED:

36-11-72. The board shall promulgate rules pursuant to chapter 1-26 to provide for the regulation of telepharmacy in this state. The rules must provide for:

(1) License and renewal application requirements, including:
   (a) Establishment of an initial license fee and a renewal fee, each not to exceed two hundred fifty dollars;
   (b) Procedures for the reinstatement of an expired license; and

(c) Establishment of a late fee for reinstating an expired license, not to exceed fifty dollars;

(2) Minimum structural, security, and equipment requirements for the remote pharmacy;

(3) Minimum staffing requirements for the central pharmacy and remote pharmacy;

(4) Record keeping requirements for the central pharmacy and remote pharmacy;

(5) Policies and procedures for the daily operation of the remote pharmacy; and

(6) Use of automated dispensing machines.

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

If the majority of ownership of a remote pharmacy changes, the new owners must, within thirty days after the ownership change:

(1) Submit the renewal application prescribed by the board, as provided in § 36-11-72, indicating the change of ownership; and

(2) Pay the renewal fee established by the board, as provided in § 36-11-72.

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

36-11A-8. To apply for a wholesale or other drug distributor license, a person must submit an application on a form provided by the board and pay an annual license fee set by the board, not to exceed five hundred dollars.

All financial statements or related information submitted by applicants must be treated as confidential materials.

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

36-11A-13. Each wholesale drug distributor license expires on December thirty-first following the date of issuance. The board shall provide an application for license renewal to each licensee before December first of each year. To renew a license, the licensee shall submit the renewal application and pay the annual license fee set by the board as provided in § 36-11A-8. If application for renewal of the license accompanied by the annual license fee is not made before the expiration date, the existing license lapses on the date of expiration. If the board receives a renewal application and fee for an expired license, the board must assess a fifty-dollar late fee and may reinstate the license.

If the majority of ownership of a licensed facility changes, the new owners must, within thirty days after the ownership change:

(1) Submit a renewal application, indicating the change of ownership; and

(2) Pay a fee equal to the annual license fee.

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

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

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

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

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

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

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

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

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

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

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

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:

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 board, for a license to engage in the distribution of prescription drugs. Each application must be accompanied by a license fee of 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.

Law Implemented: SDCL 36-11A-7, 36-11A-8.

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

I certify that the attached Act originated in the:

House as Bill No. 1016

_____
Chief Clerk

_____
Speaker of the House

Attest:

_____
Chief Clerk

_____
President of the Senate

Attest:

_____
Secretary of the Senate

House Bill No. 1016
File No. _____
Chapter No. _____

Received at this Executive Office
this _____ day of _____,

2025 at _____M.

By _____
for the Governor

The attached Act is hereby
approved this _____ day of
_____, A.D., 2025

_____
Governor

STATE OF SOUTH DAKOTA,

ss.

Office of the Secretary of State

Filed _____, 2025
at _____ o'clock __M.

_____
Secretary of State

By _____
Asst. Secretary of State