2026 South Dakota Legislature

Senate Bill 14

Introduced by: The Chair of the Committee on Health and Human Services at the request of the State Board of Pharmacy

An Act to modify provisions related to the practice of pharmacy.

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

Section 1. 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/, and 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, a process, a biotechnological entity, a 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) "Pharmacist-in-charge," a pharmacist designated by a pharmacy owner to assume full legal responsibility for all professional and facility operations;

(19) "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)~~(20) "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)~~(21) "Prescription drug order," a written or oral order of a practitioner for a drug or drug device for a specific patient;

~~(21)~~(22) "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)~~(23) "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 2. That § 36-11-11 be AMENDED:

36-11-11. The Board of Pharmacy ~~may~~ shall promulgate rules pursuant to chapter 1-26:

(1) Pertaining to the practice of pharmacy;

(2) Relating to the sanitation of persons and establishments licensed under the provisions of this chapter;

(3) Pertaining to establishments licensed under the provisions of this chapter wherein any drug is compounded, prepared, dispensed, or sold;

(4) Providing for minimum equipment and standards of establishments licensed under the provisions of this chapter;

(5) Pertaining to the sale of drugs by or through any mechanical device;

(6) In cooperation with other governmental agencies where there exists a joint responsibility for protecting the public health and welfare;

(7) Pertaining to the sale of nonprescription drugs;

(8) To adopt ~~such~~ publications or supplements thereto, as ~~shall from time to time be~~ deemed necessary to describe the drugs, medicines, prescription drugs, or dispensing physician ~~or other terms defined in § 36-11-2~~;

(9) Pertaining to the posting of prescription prices on the premises of a pharmacy department to provide consumers with comparative pricing information;

(10) Pertaining to the registration of drug wholesalers and manufacturers;

(11) Pertaining to home health care and service;

(12) Pertaining to computerized pharmacy;

(13) Pertaining to the registration of registered pharmacy technicians; an annual registration fee not to exceed thirty dollars; and tasks that may not be delegated by a licensed pharmacist to a registered technician;

(14) ~~Redispensing~~ Pertaining to the redispensing of pharmaceuticals; ~~and~~

(15) Pertaining to the dispensing of biological products; and

(16) Pertaining to remote drop sites, as authorized in section 10 of this Act.

Section 3. That § 36-11-32 be AMENDED:

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

(1) ~~Submits~~A pharmacist who is the owner, or part owner, of the merchandise and fixtures of the place of business for which the pharmacy license is applied for, provided:

(a) The pharmacist will serve as the pharmacist-in-charge; or

(b) The pharmacist has submitted an affidavit, on a form prescribed by the board, delegating complete responsibility for the pharmaceutical services in the place of business to another pharmacist-in-charge; or

(2) A non-pharmacist owner of the merchandise and fixtures of the place of business for which the pharmacy license is applied for, provided the owner has submitted an affidavit on a form prescribed by the board delegating complete responsibility for the pharmaceutical services in the place of business to a pharmacist-in-charge.

The applicant for the pharmacy license shall submit a form prescribed by the board~~;~~ ~~and~~

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

Section 4. 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~~ owner of the proposed pharmacy 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~~ owner:

(a) Is a pharmacist and will serve as the pharmacist-in-charge; or

(b) Submits an affidavit, on a form prescribed by the board, delegating complete responsibility for the pharmaceutical services in the proposed pharmacy to a pharmacist-in-charge.

The ~~pharmacist~~ pharmacist-in-charge must ensure all staff 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 5. That § 36-11-35 be AMENDED:

36-11-35. Each pharmacy license expires on June thirtieth following the date of ~~issue~~ issuance. To renew a pharmacy license, the ~~pharmacist~~ owner 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 6. That § 36-11-37 be AMENDED:

36-11-37. A pharmacy ~~license may be transferred to another pharmacist~~ owner may change the designation of the pharmacist-in-charge, provided an application for the ~~transfer of the license~~ change 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~~ change 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~~ owner must reapply for the license.

When a change in the designation of a pharmacist-in-charge occurs, an on-hand inventory of controlled substances, as listed in chapter 34-20B, must be completed. The inventory must be taken on the date the new pharmacist-in-charge assumes active management of the pharmacy. The inventory list must be retained in the pharmacy for two years from the date of the inventory.

Section 7. That § 36-11-38 be AMENDED:

36-11-38. In the event of the death of the ~~pharmacist in active management~~ pharmacist-in-charge, 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~~ designation of the pharmacist-in-charge is changed as provided in § 36-11-37.

Section 8. 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.

The delivery of a drug or drug device to a patient outside of a pharmacy by courier, mail, or remote drop site is not considered a violation of this chapter, if done so under the supervision of a pharmacist in a licensed pharmacy.

Section 9. 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~~ pharmacist-in-charge;

(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~~ change in designation of the pharmacist-in-charge, 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 owner ceased to be in active management of the pharmacy, without a change in designation of the pharmacist-in-charge, as provided in § 36-11-37; ~~or~~

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

(8) The majority ownership of the pharmacy changed without the change being reported as provided in § 36-11-35.

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

Section 10. That a NEW SECTION be added to chapter 36-11:

A licensed pharmacy may utilize a remote drop site to deliver prescription drugs to patients if:

(1) The remote drop site is under the supervision of the pharmacist-in-charge; and

(2) The prescription drugs are prepared by, and remain under the control of, the pharmacy.

A remote drop site is not required to be separately licensed as a pharmacy.

Section 11. That § 36-11-34 be REPEALED.

~~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.~~