

ARTICLE 20:51

PHARMACISTS

Chapter

- 20:51:01 Registration by examination.
- 20:51:02 Internship requirements.
- 20:51:03 Interns in clinical projects, Repealed.
- 20:51:04 Registration by reciprocity.
- 20:51:05 Restricted professional practices.
- 20:51:06 Pharmacy practice and registration.
- 20:51:07 Minimum equipment requirements.
- 20:51:08 Self-service restrictions.
- 20:51:09 Nonprescription drugs.
- 20:51:10 Poisons.
- 20:51:11 Patent and proprietary medicines, Repealed.
- 20:51:12 Wholesale drugs and medicines, Repealed.
- 20:51:13 Special restrictions.
- 20:51:14 General administration.
- 20:51:15 Pharmacies in hospitals, nursing facilities, or related facilities.
- 20:51:16 Rules of professional conduct.
- 20:51:17 Automated mechanical distribution devices.
- 20:51:18 Posting of prescription drug prices, Repealed.
- 20:51:19 Continuing education.
- 20:51:20 Computer pharmacy.

- 20:51:21 Unit dose systems.
- 20:51:22 Support personnel.
- 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- 20:51:26 Sterile products for home care patients, Repealed.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.
- 20:51:28 Administration of influenza immunizations.
- 20:51:29 Registered pharmacy technicians.
- 20:51:30 Telepharmacy.
- 20:51:31 Sterile 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.

CHAPTER 20:51:35

DONATED PRESCRIPTION DRUG AND MEDICAL SUPPLY REDISPENSING PROGRAM

Section

- 20:51:35:01 Definitions.
- 20:51:35:02 Eligibility criteria for participating pharmacies.
- 20:51:35:03 Criteria for donating and accepting donated prescription drugs and supplies.
- 20:51:35:04 Prescription drugs which may not be donated or accepted.

20:51:35:05 Inspecting and documenting donated prescription drugs and supplies.

20:51:35:06. Acceptance, storage, and destruction of donated prescription drugs and supplies.

20:51:35:07 Return or destruction of donated controlled substances.

20:51:35:08 Recalls.

20:51:35:09 Criteria for dispensing donated prescription drugs and supplies.

20:51:35:10 Acceptance form for individuals to receive donated prescription drugs and supplies.

20:51:35:11 Handling fee.

20:51:35:01. Definitions. Terms defined in SDCL 34-20H-1 have the same meaning when used in this chapter. Terms used in this chapter mean:

(1) "Board," South Dakota Board of Pharmacy as defined in SDCL 36-11-2(3);

(2) "Controlled substance," the substances described, defined, or provided in SDCL 34-20B-11 to 34-20B-26, inclusive;

(3) "Donor," any natural person or entity legally authorized to possess drugs with a license or permit in good standing in the state in which it is located, and government agencies and entities that are federally authorized to possess drugs;

(4) "Eligible patient," an indigent, uninsured, or underinsured person;

(5) "Health care facility," a:

(a) Facility licensed pursuant to SDCL chapter 34-12; or

(b) Similar licensed facility located in another state;

(6) "Health care professional," a:

(a) Physician licensed pursuant to SDCL chapter 36-4;

(b) Certified nurse practitioner or certified nurse midwife licensed pursuant to SDCL chapter 36-9A;

(c) Physician assistant licensed pursuant to SDCL chapter 36-4A;

(d) Dentist licensed pursuant to SDCL chapter 36-6A;

(e) Optometrist licensed pursuant to SDCL chapter 36-7;

(f) Podiatrist licensed pursuant to SDCL chapter 36-8; or

(g) Pharmacist licensed pursuant to SDCL chapter 36-11;

(7) "Indigent individual," any person who does not have sufficient money, credit, or insurance to pay for prescribed medication;

(8) "Pharmacist-in-charge," as defined in §20:51:06:02.01;

(9) "Prescription Drugs," legend drugs as defined in SDCL 34-20B-28.1; and

(10) "Program," the donated prescription drug and medical supply redispensing program established by the board pursuant to SDCL chapter 34-20H.

Source:

General Authority: SDCL 34-20H-7.

Law Implemented: SDCL 34-20H-7.

Cross-Reference: Drugs and Substances Control, SDCL chapter 34-20B.

20:51:35:02. Eligibility criteria for participating pharmacies. Participation in the program is voluntary. In order to participate, a pharmacy must:

(1) Comply with all applicable federal and state laws and hold an active, nonrestricted, board-issued license in good standing; and

(2) Submit on a form provided by the board:

(a) The pharmacy name, street address, telephone number, and board-issued license number;

(b) The name and license number of the pharmacist-in-charge as defined in § 20:51:06:02.01; and

(c) A statement, signed and dated by the pharmacist-in-charge, indicating that the pharmacy meets the eligibility requirements under this section and that all pharmacists shall comply with the requirements of this chapter.

A pharmacy may withdraw from participation in the program at any time by providing written notice to the board on a form prescribed by the board.

Source:

General Authority: SDCL 34-20H-7(2)(5).

Law Implemented: SDCL 34-20H-4.

20:51:35:03. Criteria for donating and accepting donated prescription drugs and supplies. A participating pharmacy may only accept the following donations from natural persons eighteen years or older or entities, who are in lawful possession of the donation:

(1) A prescription drug that:

(a) Is in its original sealed and tamper-evident packaging. However, a drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit package is not opened;

(b) Has packaging containing the lot number and expiration date of the drug. If the lot number is not retrievable, all specified medications must be destroyed in the event of a recall;

(c) Has an expiration date that is more than six months after the date the drug was donated. A donated prescription drug bearing an expiration date that is six months or less after the date the prescription drug was donated may be accepted and distributed if the drug is in high demand and can be dispensed for use prior to the drug's expiration date;

(d) Has no physical signs of tampering, misbranding, deterioration or adulteration, whether to the drug itself or its packaging, and there is no reason to otherwise believe that the drug is adulterated;

(e) If the drug has not been continually under the control of a health care professional, a pharmacy, or other legally authorized entity allowed to possess prescription drugs, the participating pharmacy must collect a donation form that is signed by the donor or that person's authorized representative attesting to the manufacturer's recommended proper storage of the prescription drug.

(2) A medical supply that is:

(a) In its original, unopened, sealed packaging; and

(b) Not adulterated or misbranded.

Source:

General Authority: SDCL 34-20H-7(2)(3)(5).

Law Implemented: SDCL 34-20H-2.

20:51:35:04. Prescription drugs which may not be donated or accepted. In addition to the grounds for donation rejection in SDCL 34-20H-2, no prescription drug that requires storage temperatures other than normal room temperature, as specified by the manufacturer, may be donated

or accepted except a drug donated directly from a drug manufacturer or other entity authorized to possess prescription drugs.

Source:

General Authority: SDCL 34-20H-7(2).

Law Implemented: SDCL 34-20H-2, 34-20H-4(1).

20:51:35:05. Inspecting and documenting donated prescription drugs and supplies. A

pharmacist-in-charge designated pharmacist at the participating pharmacy shall inspect a donated prescription drug or medical supply to determine, to the extent reasonably possible, that the drug or supply is not adulterated or misbranded, is safe and suitable for dispensing, and is not ineligible. The pharmacist who inspects the drug or supply shall sign the donor form stating the above. If a participating pharmacy receives a drug or medical supply from another participating pharmacy, the receiving participating pharmacy does not need to reinspect the drug or supply when receiving a copy of the donor form with the inspection information. The transfer of the drug or supply from one participating pharmacy to another must be documented in both the receiving and the donating pharmacy.

After inspecting donated prescription drugs and medical supplies, the participating pharmacy must inventory and document the donation in the board's program database.

Source:

General Authority: SDCL 34-20h-4(3), 34-20H-7(2)(3)(5).

Law Implemented: SDCL 34-20H-2, 34-20H-4(3), 34-20H-9.

20:51:35:06. Acceptance, storage, and destruction of donated prescription drugs and

supplies. A participating pharmacy shall store a donated drug or medical supply in a storage area under environmental conditions appropriate for the drug or supply being stored. Donated prescription drugs and medical supplies may not be stored with nondonated inventory.

When a donated prescription drug or medical supply is not inspected immediately upon receipt, a participating pharmacy must quarantine the donation until it has been inspected and approved for dispensing under the program.

A participating pharmacy shall destroy donations that are not suitable for dispensing and make a record of the destruction.

Prescription drugs and medical supplies may be donated on the premises of a participating pharmacy to a person designated by the pharmacy. A drop box may not be used to deliver or accept donations.

Source:

General Authority: SDCL 34-20H-7(2)(3).

Law Implemented: SDCL 34-20H-3, 34-20H-4(1).

20:51:35:07. Return or destruction of donated controlled substances. A controlled substance may not be accepted for donation. A controlled substance submitted for donation must be returned immediately to the donor or the donor's representative who provided the controlled substance. In the event that a controlled substance enters the participating pharmacy and it is not practicable to return the controlled substance to the donor or the donor's representative due to an

inability to identify the donor or the donor's representative or due to the refusal by the donor or the donor's representative to receive them, the abandoned controlled substance must be documented and destroyed rendering the chemical compound to be non-retrievable per 21 C.F.R. § 1300.05(b), in effect on April 1, 2021. A pharmacist or other person with authority to dispense controlled substances shall destroy the controlled substance. Another employee of the participating pharmacy shall witness the destruction.

Source:

General Authority: SDCL 34-20H-7(2)(3).

Law Implemented: SDCL 34-20H-2, 34-20H-3.

20:51:35:08. Recalls. If a participating pharmacy receives a recall notification, the pharmacy shall perform a uniform destruction of the recalled, donated prescription drug or medical supply and complete the destruction information form for the drug or medical supply destroyed. If a recalled drug or recalled medical supply has been dispensed, the participating pharmacy shall immediately notify the recipient of the recalled drug or supply pursuant to established pharmacy recall procedures. The participating pharmacy shall remove the recalled prescription drug or supply from the program database.

Source:

General Authority: SDCL 34-20H-7(2)(5).

Law Implemented: SDCL 34-20H-4(1), 34-20H-9.

20:51:35:09. Criteria for dispensing donated prescription drugs and supplies. A donated

drug or medical supply may be dispensed only if:

(1) The drug or supply is prescribed by a health care professional for use by an eligible patient and is dispensed by a licensed pharmacist in a participating pharmacy;

(2) The participating pharmacy dispenses to an individual requesting a drug or supply through the program as follows, in descending order of priority:

(a) An indigent individual;

(b) An individual who has no active third-party prescription drug reimbursement coverage for the drug or medical supply prescribed; and

(c) Any other individual.

(3) The participating pharmacy dispenses the donated prescription drug or supply in compliance with all applicable federal and state laws and regulations for dispensing prescription drugs and supplies;

(4) The participating pharmacy dispensing the prescription drug or medical supply removes the original donor's identification and the name of the dispensing pharmacy from the package prior to dispensing the drug or supply; and

(5) The participating pharmacy documents the dispensing in the board's program database.

Source:

General Authority: SDCL 34-20H-7(1)(2)(3).

Law Implemented: SDCL 34-20H-4(1), 34-20H-7(1), 34-20H-3.

20:51:35:10. Acceptance form for individuals to receive donated prescription drugs and supplies. An individual who requests and receives a prescription drug or medical supply from the program shall, prior to receipt of the drug or medical supply, sign an acceptance form attesting that:

- (1) The individual is an eligible patient;
- (2) The individual acknowledges that the drug or supply has been donated; and
- (3) The individual waives the requirement for child-resistant packaging, if applicable.

Source:

General Authority: SDCL 34-20H-7(2)(5).

Law Implemented: SDCL 34-20H-7(1)(a)(b).

20:51:35:11. Handling fee. A participating pharmacy may charge the recipient of a donated drug or medical supply a handling fee, not to exceed twenty-five dollars, to cover mailing, handling, or dispensing costs. A prescription drug or medical supply dispensed through the program is not eligible for reimbursement under any insurance or medical assistance program.

Source:

General Authority: SDCL 34-20H-7(4).

Law Implemented: SDCL 34-20H-6