

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- 20:51:03 Interns in clinical projects, Repealed.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- 20:51:11 Patent and proprietary medicines, Repealed.
- 20:51:12 Wholesale drugs and medicines, Repealed.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- 20:51:18 Posting of prescription drug prices, Repealed.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- 20:51:26 Sterile products for home care patients, Repealed.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 repository program.

CHAPTER 20:51:35

DONATED DRUG REPOSITORY PROGRAM

Section

- 20:51:35:01 Definitions.
- 20:51:35:02 Eligibility criteria.
- 20:51:35:03 Criteria for accepting donated prescription drugs and supplies.
- 20:51:25:04 Drugs which may not be donated or accepted.

20:51:35:05 Criteria for inspecting donated prescription drugs and supplies.

20:51:35:06. Storage of donated prescription drugs and supplies.

20:51:35:07 Return 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 Eligibility criteria for individuals to receive donated prescription drugs and supplies.

20:51:35:11 Handling fee.

20:51:35:01. Definitions. Terms used in this chapter:

(1) "Controlled substance" means a drug as defined in SDCL §§ 34-20B-11 to 34-20B-26;

(2) "Donor" means any person, including an individual member of the public, or any entity legally authorized to possess drugs with a license or permit in good standing in the state in which it is located, including but not limited to a wholesaler or distributor, third party logistic providers, pharmacy, dispenser, clinic, surgical or health center, laboratory, medical or pharmacy school, prescriber or other health care professional, or healthcare facility. Donor shall also mean government agencies and entities that are federally authorized to possess drugs including but not limited to drug manufacturers, repackagers, relabelers, outsourcing facilities, and federal healthcare facilities;

(3) "Drugs" means prescription drugs as defined in SDCL chapter 36-11-2.1;

(4) "Eligible patient" means an indigent, uninsured, or underinsured person; provided, however, that if the participating pharmacy's supply of donated drugs exceed the need for donated drugs by indigent patients, then any other person in need of a particular drug can be an eligible patient;

(5) "Healthcare facility" means:

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

(b) A similar licensed facility located in another state;

(6) "Health care professional" means a:

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

(b) Certified nurse practitioner or 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" means: For the purposes of this chapter, an indigent individual is any person who does not have sufficient money, credit, or insurance to pay for prescribed medication.

(8) "Program" means the donated prescription drug repository program established by the board pursuant to SDCL §34-20H.

Source:

General Authority: SDCL 34-20H-7.

Law Implemented: SDCL 34-20H-7.

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

20:51:35:02. Eligibility criteria. Participation in the donated prescription drug repository program is voluntary. A participating pharmacy electing to participate in the program must:

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

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

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

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

(c) A statement, signed and dated by the PIC indicating that the pharmacy meets the eligibility requirements under this rule and 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)(3).

Law Implemented: SDCL 34-20H-4, 34-20H-7(2)(3).

20:51:35:03. Criteria for donating and accepting prescription donated drugs and supplies. Participating pharmacies shall only accept the following donations:

(1) A donor who is 18 years of age or older may donate legally obtained prescriptions drugs or supplies to a participating pharmacy if they meet the requirements of this rule as determined by the PIC;

(2) The participating pharmacy may accept a prescription drug only if all of the following requirements are met:

(a) The drug 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) The packaging contains the lot number and expiration date of the drug. If the lot number is not retrievable, all specified medications will be destroyed in the event of a recall;

(c) The drug has an expiration date that is more than six months after the date that 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) Neither the drug nor the packaging has any physical signs of tampering, misbranding, deterioration or adulteration, and there is no reason to believe that the drug is adulterated;

(e) All donated eligible drugs received by the participating pharmacy shall be documented in the board's electronic database of drugs and supplies and shall be accompanied by a donor form with an agreement to donate; and

(f) 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 proper storage.

(6) A participating pharmacy may accept supplies necessary to administer prescription drugs only if all of the following requirements are met:

(a) The supplies are in their original, unopened, sealed packaging;

(b) The supplies are not adulterated or misbranded; and

(c) All supplies shall be inventoried at the participating pharmacy and documented in the board repository database. The documentation shall be provided on a form provided by the board and shall include a description of the supplies and the date donated.

(7) Drugs and 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-2, 34-20H-7(2)(3)(5), 34-20H-9.

20:51:35:04. Drugs which may not be donated or accepted. In addition to the prohibitions in SDCL 34-20G-2, no drug that requires storage temperatures other than normal room temperature as specified by the manufacturer may be donated or accepted because of the increased potential for these drugs to become adulterated. Excluded from this restriction are drugs donated directly from a drug manufacturer or other entity authorized to possess prescription drugs

Source:

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

Law Implemented: SDCL 34-20H-2, 34-20H-7(2)(3).

20:51:35:05. Criteria for inspecting donated prescription drugs and supplies. A PIC designated pharmacist at the participating pharmacy shall inspect donated prescription drugs and supplies to determine, to the extent reasonably possible in the judgment of the pharmacist, that the drugs and supplies are not adulterated or misbranded, are safe and suitable for dispensing, and are not ineligible drugs or supplies. The pharmacist who inspects the drugs shall sign the donor form stating

the above. If a participating pharmacy receives drugs and supplies from another participating pharmacy, the receiving participating pharmacy does not need to reinspect the drugs and supplies when receiving a copy of the donor form with the inspection information. The transfer of the medications from one participating pharmacy to another shall be documented in both the receiving and the donating pharmacy.

Source:

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

Law Implemented: SDCL 34-20H-2, 34-20H-7(2)(3).

20:51:35:06. Storage of donated prescription drugs and supplies. The participating pharmacy shall store donated drugs and supplies in a storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies may not be stored with nondonated inventory.

When donated drugs are not inspected immediately upon receipt, a participating pharmacy shall quarantine the donated drugs until the donated drugs have been inspected and approved for dispensing under the program.

Participating pharmacies shall destroy donated drugs that are not suitable for dispensing and make a record of the destruction.

Source:

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

Law Implemented: SDCL 34-20H-3, 34-20H-7(2)(3).

20:51:35:07. Return of donated controlled substances. Controlled substances shall not be accepted for donation. Controlled substances submitted for donation shall be returned immediately to the donor or the donor's representative who provided the drugs. In the event that controlled substances enter the participating pharmacy and it is not possible or practicable to return the controlled substances to the donor or the donor's representative due to inability to identify the donor or the donor's representative or due to refusal by the donor or the donor's representative to receive them, abandoned controlled substances shall be documented and destroyed rendering the chemical compound of the drug to be nonretrievable per 21 CFR § 1300.05(b). Such destruction shall be performed by a pharmacist or other person with authority to dispense controlled substances and shall be witnessed by another employee of the participating pharmacy.

Source:

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

Law Implemented: SDCL 34-20H-2, 34-20H-3, 34-20H-7(2)(3).

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

Source:

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

Law Implemented: SDCL 34-20H-3, 34-20H-7(2)(3).

20:51:35:09. Criteria for dispensing donated prescription drugs and supplies. Donated drugs and supplies may be dispensed only if the drugs or supplies are prescribed by a health care practitioner for use by an eligible individual and are dispensed by a licensed pharmacist.

(1) A participating pharmacy shall prioritize dispensing to an individual requesting drugs through the program as follows:

(a) An indigent individual;

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

(c) Any other individual.

(2) A participating pharmacy shall dispense donated prescription drugs in compliance with applicable federal and state laws and regulations for dispensing prescription drugs, including all requirements relating to packaging, labeling, record keeping, drug utilization review, and patient counseling.

(3) The participating pharmacy shall remove the original donor's identification and the name of the dispensing pharmacy from the package prior to dispensing the drugs or supplies.

Source:

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

Law Implemented: SDCL 34-20H-4(1), 34-20H-7(1)(2)(3).

20:51:35:10. Eligibility criteria for individuals to receive donated prescription drugs and supplies. An individual who requests and receives drugs from the donated prescription drug repository program shall sign an acceptance form attesting to the following:

(1) The individual meets the definition of eligible patient in § 20:51:35:1(4);

(2) The individual acknowledges that the drugs have been donated; and

(3) The individual consents to a waiver of the requirement for child resistant packaging of the

Poison Prevention Packaging Act.

Source:

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

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 a handling fee, not to exceed a maximum of \$25 to cover mailing, handling, or dispensing costs. A prescription drug dispensed through the prescription drug donation repository program shall not be eligible for reimbursement under any insurance or medical assistance program.

Source:

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

Law Implemented: SDCL 34-20H-6, 34-20H-7(4)(5).