

# State-Specific Controlled Substance Requirements

Updated 6/25/23

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Biennial Inventory (DEA):	A physical inventory of all controlled substances on hand must be taken at least every <u>two years</u> . The biennial inventory may be taken on any date, which is within two years of the previous biennial or initial inventory. [21 CFR 1304.11]  NOTE:
	<ul> <li>Separate biennial inventories must be completed for schedule II and schedule III-V controlled substances.</li> </ul>
	<ul> <li>Biennials may be conducted more frequently than every two years. As a recommendation, conduct your DEA biennial inventory at the same time you conduct your annual inventory for the state.</li> </ul>
	<ul> <li>Biennial inventories must be conducted by the DEA registrant, or their designee who has been granted Power of Attorney, along with an authorized witness.</li> </ul>
	Biennial inventories must indicate whether they are conducted at the start or close of business.
	South Dakota follows the same biennial inventory guidelines as the DEA (SD Admin. R. 44:58:07:03)
CE:	<u>Veterinarian</u> : 32 hours every 2 years
	General medicine topics: 16 hours if related to the practice of veterinary medicine
	Online study: 32 hours allowed
	Every veterinarian seeking renewal of registration shall submit proof of attendance at educational programs upon the request of the board.
	See <u>Chapter 20:57:04</u> for board approved CE parameters.
	Veterinary Technician: 12 hours every 2 years
	General medicine topics: 12 hours of veterinary science courses (courses must be approved by the state association)
	Online study: 12 hours allowed
	Veterinary Dispensing Technician: a minimum of 12 credit hours in the 24 months before the submission of the renewal application.
	The continuing education may include SD Veterinary Medical Association sponsored courses and other courses relating to veterinary science and technology, including clinical techniques, diagnostics, therapeutics, animal care, and record keeping as approved by the Examining Board.
	South Dakota does not currently require controlled substance CE.
	The licensees shall maintain CE records for <b>4 years</b> after the date of the renewal license.
Compounding:	"8.2.10 Compounding of a controlled substance by a practitioner is permitted as long as the United States Pharmacopoeia (USP) 795 and 797 standards and guidelines are followed." <a href="24 Del. Admin.code">24 Del. Admin.code</a> § 8.0
	Compounding is any manipulation of a drug beyond that stipulated on the drug label. Veterinary drugs should only be compounded based on a licensed veterinarian's prescription, and to meet the medical needs of a specific patient. Manipulation might include mixing, diluting, concentrating, flavoring, or changing a drug's dosage form. Examples of compounding include:  • Mixing two injectable drugs in the same syringe  • Creating an oral suspension from crushed tablets or an injectable solution  • Adding flavoring to a commercially available drug  • Creating a transdermal gel for a drug typically taken through other routes  • Mixing two solutions for instilling into the ear
	<u>\$D Compounding</u> :



# State-Specific Controlled Substance Requirements

	"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;
Dispensing:	"Dispense" or "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;  "Distributing," the delivery of a drug or drug device other than by administration or dispensing;  S.D. Codified Laws § 36-11-2
	Verifying dispensed CS's: Dispensing of all controlled substances will be verified through prescriptions or other chronological records as follows:  (a) The records shall include the name and address of the patient (or species and name and address of the owner if the patient is an animal), the date, the controlled substance and dose, the quantity dispensed, and the name, address, and DEA number of the prescriber;  (b) A separate file shall be maintained for dispensed substances listed in Schedule II;  (c) Schedule III and IV records may be maintained in a separate file or marked with a red "C" at least one inch high and filed with the prescriptions for noncontrolled drugs. If the pharmacy uses an automated data processing system or electronic record keeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, controlled substance dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived  44:58:07:04
Diversion Reporting:	44:58:07:05. Theft reports. A registrant shall notify the division of the theft or loss of a controlled substance within 48 hours. The report shall include the names and quantities of drugs and the circumstances involved in the theft or loss.
Euthanasia:	Euthanasia may be performed by a licensed veterinarian.
Ownership:	Non-veterinarian ownership of a veterinary facility is inconclusive at this time.
Power of Attorney:	South Dakota Powers of Attorney require a notary public to oversee the signing of the document by the Principal and Agent.
Prescribing:	"Prescription drug order," a written or oral order of a practitioner for a drug or drug device for a specific patient;" S.D. Codified Laws § 36-11-2  E-prescribing: SD does not have mandated e-prescribing at this time.
PDMP:	Any person who has a controlled drug or substance registration pursuant to § 34-20B-29 to prescribe or dispense any controlled drug or substance within this state must register with the program.  Veterinarians licensed pursuant to chapter 36-12 are not subject to this requirement. The program shall work with the Department of Health to assure compliance with the requirement.  34-20E-2.1
	<b>Veterinarians are exempted from enrollment as data requesters</b> for the South Dakota Prescription Drug Monitoring Program (SD PDMP).



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Registration Veterinary Medical Corporation Act
One or more persons licensed pursuant to chapter 36-12, hereinafter referred to as the Veterinary Practice Act, may associate to form a corporation, pursuant to the provisions of law pertaining to private corporations to own, operate, and maintain an establishment Fee: \$50  Registration Application  Attach copies of articles of incorporation and corporate bylaws.
<ul> <li>In the event amendments are made, such amendments shall be submitted to the secretary of the board of veterinary medical examiners, 411 S Fort Street, Pierre, SD 57501.</li> </ul>
<u>Patient records</u> : 20:51:24:04. Maintenance of records. A pharmacy shall maintain information in a patient record system for <b>at least one year from the date of the last entry in the record</b> . The information must be readily retrievable and may be maintained in an electronic data system or as a paper copy.
Controlled substance records: retain for a minimum of <b>two years</b> .
Schedule III:  Ephedrine
Schedule IV:  Pyrovalerone
<ul><li>Ezogabine</li><li>Lacosamide</li><li>Pregabalin</li></ul>
South Dakota <b>does require</b> DEA registrant practitioners to obtain a second state controlled substance registration (South Dakota Controlled Substance Registration (SD CSR"), before obtaining a DEA registration, as well as an active Veterinary Medical Professional License to practice in South Dakota.
SD CSR's are managed through the South Dakota Department of Health's registration system: <a href="https://apps.sd.gov/PH04ControlledSubstance/">https://apps.sd.gov/PH04ControlledSubstance/</a> .
<u>SD CSR:</u> South Dakota no longer uses the DEA number and has its own South Dakota Controlled Substance Registration Number.
<ul> <li>make sure you have all supporting documentation before starting the process, and if you answer "yes" to the liability questions, make sure to provide the required information via the upload process.</li> </ul>
<ul> <li>New practitioners applying for a South Dakota Controlled Substance Registration in addition to a new Drug Enforcement Administration (DEA) registration can expect the process to take a minimum of six weeks</li> <li><u>Fee</u>: \$150 (initial &amp; renewal application)</li> </ul> Application for a new SD CRS
<ul> <li>Changes/Renewals:         <ul> <li>Moving a DEA registration to South Dakota: If you are moving your DEA number to South Dakota you must scan a copy of the registration you are moving to South Dakota. You must update your SD CSR before updating your DEA registration.</li> <li>NOTE: if you move to a new location you MUST update your registration. A registration is automatically suspended if you fail to maintain the person's professional license, fails to maintain DEA registration in South Dakota, discontinues professional practice within South Dakota, or changes name or address without notifying the secretary. (ARSD 44:58:06:02)</li> </ul> </li> <li>Renew or make changes to your registration</li> </ul>



# State-Specific Controlled Substance Requirements

	Locum Tenens SD CSR: Locum tenens practitioners registered in another state may obtain a locum tenens controlled substance registration, good for 60 days, based on their DEA registration from the state where they are licensed to practice. A start date must be provided.  • Fee: \$75
	<u>Display</u> : "No person shall practice veterinary medicine in the State of South Dakota without possessing and displaying prominently in his or her principal office a license and a current and valid certificate of registration issued pursuant to the provisions of this chapter." <u>S.D. Codified Laws § 36-12-21</u>
	<u>Instructions on obtaining an SD CRS</u>
Supervision:	36-12-21.6. Supervision of technician by veterinarian - Promulgation of rules  A veterinary technician may only work under the direction or supervision of the licensed veterinarian or veterinarians by whom the technician is employed. The State Board of Veterinary Medical Examiners shall promulgate rules pursuant to chapter 1-26 to define the terms direction and supervision.
	"The licensed veterinarian by whom a registered veterinary technician is employed is responsible for the acts of the technician, and nothing in this chapter relieves the employer of the ordinary duties and responsibilities of the acts or conduct of the employee." <u>S.D. Codified Laws § 36-12-21.8</u>
Telemedicine:	No existing law. Where telemedicine occurs is not defined.
Veterinary Professional	Veterinarians:
License:	Each person licensed by the Board of Veterinary Medical Examiners to practice veterinary medicine in this state shall procure from the secretary of the board on or before July first, on a biennial basis, a certificate of registration. No licensed person applying for a certificate of registration after July first may be issued a certificate without paying a late fee not to exceed one hundred dollars.  S.D. Codified Laws § 36-12-19  License to Practice Veterinary Medicine & Surgery Application  Fee: \$75  Renewal: Biannual license fee is \$100.00 on odd numbered years. For those obtaining licensure on even numbered years an annual fee of \$50.00 must be submitted for license. (Therefore total fees to be submitted if you are taking exam on odd numbered years is \$175.00; or if you are taking exam on an even numbered year the total fee to submit is \$125.00.)
	<ul> <li>Registered Veterinary Technicians:         Application     </li> <li>Fee: \$20</li> <li>Renewal: annually each year before the first day of July of each year. The fee for renewal of the certificate shall be set by the board, and may not exceed the sum of \$5. Failure to renew a certificate on or before July first of each year constitutes a forfeiture of the registration certificate. S.D. Codified Laws § 36-12-21.5</li> <li>The board shall issue a registration certificate for each veterinary technician registered with the board. The certificate shall state the name of the licensed veterinarian by whom such technician is employed and the year of registration. The registration certificate shall be posted in the office of the licensed veterinarian per 36-12-21.4.</li> </ul>
VCPR:	VCPR must be established in-person and only applies to one veterinarian.
	South Dakota follows the federal VCPR definition, which states that a valid VCPR exists when:  A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;



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- There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
   The practicing veterinarian is readily available for follow-up in case of adverse reactions or
- The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy.

### Information and Resources

### FEDERAL:

Drug Enforcement Administration, Omaha Division 7300 World Communications Drive Omaha, NE 68122

Phone: (402) 965-3600

#### **Local DEA Offices**

Rapid City - (605) 434-4947Sioux Falls -(605) 330-4421

Federal Law: <a href="www.deadiversion.usdoj.gov">www.deadiversion.usdoj.gov</a> Controlled Substances Act: 21 USC 801 – 904

Code of Federal Regulations: <u>21 CFR Part 1300 – 1399</u>

NDC drug: <a href="https://www.fda.gov/Drugs/DevelopmentApprovalProcess/UCM070829">www.fda.gov/Drugs/DevelopmentApprovalProcess/UCM070829</a>
Diversion Control Division: <a href="https://www.deadiversion.usdoj.gov/schedules/">https://www.deadiversion.usdoj.gov/schedules/</a>

### **STATE:**

South Dakota Board of Veterinary Medical Examiners website:

https://sdvetmed.org/resources/licensing-information/

South Dakota Board of Pharmacy website: https://doh.sd.gov