ARTICLE 44:90

MEDICAL CANNABIS

Chapter

44:90:01 Definitions.

44:90:02 Registry identification cards.

44:90:03 Registration certificates.

44:90:04 Establishments.

44:90:05 Cannabis cultivation facilities.

44:90:06 Cannabis testing facilities.

44:90:07 Cannabis product manufacturing facilities.

44:90:08 Cannabis dispensaries.

44:90:09 Sampling and testing.

44:90:10 Packaging, labeling, and advertising.

44:90:11 Recordkeeping.

44:90:12 Enforcement.

44:90:13 Petitions to recognize debilitating medical conditions.

DOH DRAFT RULES

CHAPTER 44:90:01

DEFINITIONS

44:90:01:01. Definitions.

Terms defined in SDCL 34-20G-1 shall have the same meaning in this article. In addition, terms used in this article mean:

(1) "Agent identification badge," means a credential issued by the department to an establishment for the use by an agent while performing work-related duties;

(2) "Allowable quantity of cannabis products," means an amount of cannabis products that may be possessed by a cardholder or nonresident cardholder pursuant to SDCL 34-20G-1(1)(b);

(3) "Analyte," means a chemical, compound, element, bacteria, yeast, fungus, or toxin that is identified or measured by testing;

(4) "Analytical test," means the use of a single technology to detect the presence or concentration of a single analyte on one or more matrices;

(5) "Batch identifier," means a unique number or code assigned by an establishment to a quantity of cannabis, cannabis extract, or cannabis products for testing;

(6) "Cannabis beverage," means a liquid edible cannabis product with a concentration of less than 1 mg of THC per ounce of liquid;

(7) "Cannabis extract," means the resin extracted from any part of a cannabis plant;

(8) "Cannabis oil," means an edible cannabis product using a food safe oil as the primary ingredient;

DOH DRAFT RULES

(9) "Cannabis waste," means cannabis flower or trim, cannabis seeds, cannabis products, byproducts containing cannabis, or cannabis plants, excluding stalks without trichomes and root balls, that are unfit for retail transfer to another cannabis establishment;

(10) "Certificate of analysis," means a written report of the results of analytical testing, including whether the results indicate compliance with this article;

(11) "Chain of custody," means documentation of the handling of cannabis and cannabis products to ensure the accuracy of cannabis testing and preventing diversion;

(12) "Collective," means two or more cardholders who physically assist each other in the act of cultivation or processing of cannabis for medical use, except that the sharing of an enclosed, locked facility for cultivation by two or more cardholders in their own dwelling shall not be considered a collective;

(13) "Competitive application," means a medical cannabis establishment application that is scored numerically by the department, in cases where more applicants apply than are allowed by the local government;

(14) "Concentrated cannabis," means cannabis extract or a compound, manufacture, salt, derivative, mixture, or preparation from such resin, including hashish;

(15) "Equivalent cannabis weight," means the weight, in ounces, that a given quantity of cannabis product counts against the total allowable amount of cannabis under 34-20G-1(1);

(16) "Exit packaging," means a bag (single use or reusable), box, or other container for use in transporting cannabis, cannabis extract, or cannabis products after purchase at a dispensary;

(17) "Extended plant count," means the authorized cultivation of more than three plants simultaneously for a single patient's use;

DOH DRAFT RULES

(18) "Flower," means the pistillate reproductive organs of a mature cannabis plant, whether processed or unprocessed, including the flowers and buds of the plant;

(19) "Immature plant," means a cannabis plant that is larger than a seedling but has not yet flowered;

(20) "Index factor," means the annual percentage change in the consumer price index for urban wage earners and clerical workers as computed by the Bureau of Labor Statistics of the United States Department of Labor, for the year immediately preceding the year of adjustment;

(21) "Inhaled cannabis product," means cannabis concentrate or a cannabis product that is intended to be consumed by inhalation, including pre-rolled cannabis cigarettes, vaporizer cartridges, and vaporizer pens;

(22) "Inherently hazardous substance," means any solvent or chemical, other than ethanol, with a flash point at or lower than 100 degrees Fahrenheit;

(23) "Inventory record," means a daily electronic record of all cannabis, including seeds, seedlings, plants, extracts, or products;

(24) "Inventory tracking system," means an electronic system specified by the department for the purposes of identifying and preventing diversion and protecting patients from unsafe cannabis, cannabis extracts, or cannabis products;

(25) "ISO/IEC 17025 accreditation," means accreditation by the International Accreditation Service (IAS), the American Association for Laboratory Accreditation (A2LA), the ANSI National Accreditation Board (ANAB), or another laboratory accreditation board that the testing facility meets *General Requirements for the Competence of Testing and Calibration*

DOH DRAFT RULES

Laboratories developed by the International Organization for Standardization and the International Electrotechnical Commission for a particular analyte and technology;

(26) "Low-income qualifying patient," means a qualifying patient whose household has a gross monthly income that is 130 percent or less of the federal poverty level;

(27) "Marketing layer," means the outermost layer of a retail sale container, which is most predominantly apparent and visible;

(28) "Matrix," means a component or substrate that contains an analyte being tested for;

(29) "Mature plant," means a cannabis plant that has flowered;

(30) "Method," means a body of procedures and techniques for performing an activity, including sampling, chemical analysis or quantification, systematically presented in the order in which they are to be executed;

(31) "Nationally recognized testing laboratory," means an independent laboratory recognized by the Occupational Health and Safety Administration pursuant to 29 CFR section 1910.7 (2020);

(32) "Non usable," means unfit for sale or transfer;

(33) "Sample identifier," means a unique number or code assigned to a sample to be tested by a testing facility, either by the establishment submitting the sample or an agent of the testing facility;

(34) "Seedling," means a nonflowering cannabis plant or rooted cutting that measures 24 inches or less from the base of the main plant stalk to the most distant point of the plant's leaf stems or branches;

DOH DRAFT RULES

(35) "Synthetic," means formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources;

(36) "Technology," means a specific arrangement of analytical instruments, detection systems and/or preparation techniques;

(37) "Testing sample record," means a daily electronic record maintained by an establishment of batch identifiers, sample identifiers, and associated information;

(38) "THC," means delta-9 tetrahydrocannabinol;

(39) "Tincture," means a liquid edible cannabis product with a concentration of greater than 1 mg of THC per ounce of liquid in the form of ethanol, propylene glycol, glycerin, or food safe oil;

(40) "Topical cannabis product," means a non-edible cannabis product that is intended to be applied topically, including salves, creams, lotions, transdermal patches, or balms;

(41) "Transaction record," means a daily electronic record created and maintained by a dispensary to track transactions with patients;

(42) "Transfer record," means a daily electronic record of any acquisition of seeds, seedlings, plants, cannabis, or cannabis products and any transfer of cannabis or cannabis products to another medical cannabis establishment;

(43) "Trim," means trichome-containing leaves of the cannabis plant that have been intentionally removed during cultivation; and

(44) "Valid form of personal identification," means an unexpired form of identification acceptable for voter identification pursuant to SDCL section 12-18-6.1.

Source:

DOH DRAFT RULES

General Authority:

Law Implemented:

Reference: International Organization for Standardization & International Electrotechnical Commission. (2018). *ISO/IEC 17025:2017: General Requirements for the Competence of Testing and Calibration Laboratories.* https://www.iso.org/standard/66912.html

CHAPTER 44:90:02

REGISTRY IDENTIFICATION CARDS

Section

44:90:02:01	Practitioner's written certification – Debilitating Medical Condition – Recommendation for medical use of cannabis.
44:90:02:02	Practitioner certification – Recommendation for cultivation of cannabis – Extended plant count.
44:90:02:03	Patient registry identification card application requirements – Initial application.
44:90:02:04	Patient designation of caregivers – Minor patients – Person responsible for making medical decisions -- Designation by residents of health care facility or residential care facility.
44:90:02:05.	Application to cultivate cannabis -- Patient designation of caregivers to cultivate cannabis.
44:90:02:06	Registry identification card renewal requirements.
44:90:02:07	Change of designation of caregivers – Change of designation to cultivate.
44:90:02:08	Nonresident registration – Required documentation.

DOH DRAFT RULES

44:90:02:09 Nonresident registration – Identification number.

44:90:02:10 Allowable quantity of cannabis products.

44:90:02:11 Fees for registry identification cards.

44:90:02:01. Practitioner's written certification – Debilitating medical condition – Recommendation for medical use of cannabis.

1. Except in connection with nonresidents, the department shall reject a written certification not issued by a physician currently licensed pursuant to SDCL chapter 36-4.
2. A practitioner's written certification shall be on a form supplied by the Department and shall include:
   (A) The practitioner's name and address;
   (B) The practitioner's South Dakota medical license and National Practitioner Identification numbers;
   (C) Certification that the practitioner has assessed the patient's medical history and current medical condition, including an in-person physical examination;
   (D) The date on which the physical examination was conducted;
   (E) Certification that the patient has a debilitating medical condition, as defined by 34-20G-1(8), specifying the International Classification of Diseases, Tenth Revision (ICD-10) code;
   (F) Certification that the practitioner and patient have discussed treatment options for the patient's debilitating medical condition, including the benefits and risks of the medical use of cannabis;
   (G) Certification that the practitioner is available for further consultation with the patient as required;

DOH DRAFT RULES

(H) The date, if applicable, on which the patient's need for the medical use of cannabis is expected to end; and

(I) The number of caregivers, if more than one, that the patient's age or medical condition necessitates.

Source: _

General Authority: SDCL 34-20G-72(4)

Law Implemented: SDCL 34-20G-29

Reference: National Center for Health Statistics. (2021). *International Classification of Diseases, 10th Revision, Clinical Modification*. https://icd10cmtool.cdc.gov/

44:90:02:02. Practitioner certification – Recommendation for cultivation of cannabis – Extended plant count.

1. Except in connection with nonresidents, the department shall reject a recommendation for the cultivation of cannabis not issued by a physician currently licensed pursuant to SDCL chapter 36-4.

2. Unless the practitioner specifies otherwise, a recommendation to allow cultivation of cannabis shall be for three plants and shall expire on the same date as the patient's registry identification card.

3. If the practitioner recommends the cultivation of more than three plants, the recommendation shall specify the reasons for the extended plant count, including:

DOH DRAFT RULES

(A) The research on which the practitioner relied in calculating the amount of cannabis required by the patient and that the risks associated with using that amount of cannabis are outweighed by the benefits;

(B) The difficulty the patient would experience in obtaining an adequate supply of cannabis from dispensaries due to the patient's place of residence or level of disability;

(C) The practitioner's reasoning as to why the extended plant count does not create an undue risk of diversion or abuse; and

(D) Any other factors justifying the recommendation.

4. A recommendation for the cultivation of more than three plants shall expire 90 days after the date of the recommendation.

Source: _

General Authority: SDCL 34-20G-72(4)

Law Implemented: SDCL 34-20G-29

44:90:02:03. Patient registry identification card application requirements – Initial application.

A person with a debilitating medical condition, or the person responsible for making medical decisions for that person, must apply for a patient registry identification card by submitting:

1. A completed application on a form supplied by the Department, which shall contain all information required by SDCL 34-20G-29 and 34-20G-33;
2. A completed practitioner certification on a form supplied by the Department;
3. A photocopy of a valid form of personal identification;
4. A photograph meeting all requirements for a United States passport;

DOH DRAFT RULES

5. If a low-income patient, documentation of household income, including:
   (A) If employed, wage stubs or earning statements for the past 30 days;
   (B) If self-employed, most recent federal income tax return and self-employment ledgers;
   (C) Proof of all other income (including Social Security, Supplemental Security Income, workers' compensation, unemployment benefits, Bureau of Indian Affairs general assistance, child support, rental income, veterans' benefits, pensions, and interest income) for the previous 12 months; and
   (D) Most recent financial statement from checking accounts, savings accounts, certificates of deposit, credit union accounts, retirement accounts, stocks, bonds, or dividends; and
6. The required fee, pursuant to ARSD 44:90:02:11.

Source: _

General Authority: SDCL 34-20G-72(4)

Law Implemented: SDCL 34-20G-29 and 34-20G-33

44:90:02:04. Patient designation of caregivers – Minor patients – Person responsible for making medical decisions -- Residents of health care facility or residential care facility.

1. A qualifying patient may designate an eligible individual as a caregiver by submitting:
   (A) A completed designation on a form supplied by the Department;
   (B) The caregiver's sworn statement that the caregiver has not been convicted of a disqualifying felony offense in the previous 10 years;
   (C) Any additional fees.
2. A qualifying patient under 21 years of age must designate at least one caregiver.

DOH DRAFT RULES

3. Each person designated as a caregiver to one or more qualifying patients shall submit to the Division of Criminal Investigation once every 2 years:
   (A) A photocopy of a valid form of personal identification;
   (B) A Division of Criminal Investigation fingerprint card processed by a local law enforcement agency;
   (C) An authorization and release form releasing the results of a state-only background check to the department, and payment of any fee charged by the Division of Criminal Investigation.
4. A caregiver must submit a photograph meeting all requirements for a United States passport once every 5 years.
5. A caregiver must acknowledge in writing the prohibition of remuneration other than direct costs incurred for assisting with the registered qualifying patient's medical use of cannabis, pursuant to SDCL 34-20G-2(2).
6. If a practitioner has recommended that a patient younger than 18 years of age have multiple caregivers, the custodial parents or legal guardians may designate other caregivers as advised.
7. The person responsible for making medical decisions for a qualifying patient 18 years of age or older, if qualified to be a caregiver, shall be designated caregiver to the qualifying patient. If the practitioner has recommended that the patient have multiple caregivers, the person responsible for making medical decisions may designate other caregivers as advised.
8. The designation of a caregiver who is an employee of a health care facility or residential care facility to act as a caregiver on the premises of the facility requires the signature of an officer of the facility.

DGH DRAFT RULES

9. The designation shall have the same expiration date as the expiration of the qualifying patient's registry identification card.

Source: __

General Authority: SDCL 34-20G-72(4)

Law Implemented: SDCL 34-20G-1(10), 34-20G-2(2), 34-20G-30, SDCL 34-20G-31, 34-20G-33, 34-20G-35, and 34-20G-39

44:90:02:05. Application to cultivate cannabis -- Patient designation of caregivers to cultivate cannabis.

1. A patient applying to cultivate cannabis or designate a caregiver to cultivate cannabis on the patient's behalf must submit:
   (A) A practitioner's recommendation for the cultivation of cannabis;
   (B) A diagram and photographs of the enclosed, locked facility in which the cannabis will be cultivated; and
   (C) The fee required by ARSD 44:90:02:11.
2. A qualifying patient under 21 years of age may not cultivate cannabis but may designate a caregiver to cultivate cannabis on the patient's behalf.
3. Upon approval of the application, the Department will issue a two-part registry identification card to the patient or caregiver designated to cultivate cannabis:
   (A) One part of the registration card must be posted inside the enclosed, locked facility in which the cannabis is cultivated; and
   (B) The other part of the registration card must be carried by the patient or caregiver.
4. Only one person may cultivate cannabis on behalf of a patient, except that:

DOH DRAFT RULES

(A) A qualifying patient may share the designation with a designated caregiver who resides in the same dwelling; and

(B) Two custodial parents or legal guardians of a qualifying patient under 18 years of age who reside in the same dwelling may share the designation.

5. The entirety of a patient's cannabis must be cultivated in a single enclosed, locked facility.
6. No caregiver may simultaneously cultivate an extended plant count for more than one qualifying patient.
7. Two or more caregivers may not form a collective.
8. Two or more caregivers may not cultivate cannabis in a single-unit building or in a unit of a multi-unit building, unless expressly permitted by SDCL chapter 34-20G.

Source: __

General Authority: SDCL 34-20G-72(4)

Law Implemented: SDCL 34-20G-1(10), 34-20G-1(13), 34-20G-29, 34-20G-33, and 34-20G-51

44:90:02:06. Registry identification card renewal requirements.

1. A qualifying patient shall submit a renewal application, with the required fee, up to 45 days prior to the expiration of the patient's registry identification card on a form supplied by the department.
2. A qualifying patient may designate caregivers, including changing the designation, at the time of renewal on a form supplied by the Department.

Source: __

General Authority: SDCL 34-20G-72(4)

Law Implemented: SDCL 34-20G-29 and 34-20G-32

DOH DRAFT RULES

44:90:02:07. Change of designation of caregivers – Change of designation to cultivate.

1. A qualifying patient or the qualifying patient's legal representative may change the designation of caregivers at any time, including:
   (A) Substituting a new caregiver for a previously designated caregiver;
   (B) Adding an additional caregiver if recommended by a practitioner;
   (C) Adding a caregiver while a resident of a health care or residential care facility; or
   (D) If cannabis cultivation is authorized, designating a caregiver to cultivate cannabis for the patient, or changing or ending such designation.
2. The process for designating a replacement caregiver or designating an additional caregiver shall be the same as designation at the time of an initial or renewal application, with the addition of any fee for issuing new registry identification cards to the patient and all caregivers.
3. If the change results in the removal of one or more caregivers:
   (A) The patient shall notify each such caregiver in writing and shall certify to the department that notice has been given;
   (B) The caregiver shall have 15 days to return the registry identification card associated with that patient; and
4. If the application indicates that the patient no longer wishes a caregiver to cultivate cannabis on the patient's behalf or wishes a different caregiver to cultivate cannabis on the patient's behalf:
   (A) The patient shall notify the current caregiver in writing and shall certify to the department that notice has been given;

DOH DRAFT RULES

(B) The caregiver shall have 15 days to return the registry identification card and dispose of the cannabis plants and any cannabis and cannabis products that were produced from the allowable plants; and

5. A caregiver shall provide written notice to the patient or the person legally responsible for making medical decisions for the patient and shall notify the department on a form supplied by the department if the caregiver no longer wishes to act as the patient's caregiver. The caregiver shall return the registry identification card associated with the patient immediately upon submitting such notice and, if applicable, shall dispose of cannabis plants and any cannabis and cannabis products that were produced from the allowable plants.
6. Upon giving notice of a patient's death pursuant to SDCL 34-20G-46(2), a caregiver shall, within 15 days, return the registry identification card associated with the patient and, if applicable, shall dispose of cannabis plants and any cannabis and cannabis products that were produced from the allowable plants.

Source: __

General Authority: SDCL 34-20G-72(4)

Law Implemented: SDCL 34-20G-46 and 34-20G-48

44:90:02:08. Nonresident registration – Required documentation.

1. The department shall accept any of the following as sufficient documentation of a nonresident's debilitating medical condition:

   (A) Practitioner certification issued in the person's jurisdiction of residence and listing a debilitating medical condition consistent with SDCL 34-20G-1;

DOH DRAFT RULES

(B) Practitioner certification issued in the person's jurisdiction of residence, along with additional medical records indicating a debilitating medical condition recognized by the department pursuant to SDCL 34-20G-1; or

(C) Practitioner certification on a form supplied by the department.

2. The department shall accept, as a nonresident's authorization to use medical cannabis, registry identification cards or their equivalent from any state, district, territory, commonwealth, insular possession of the United States, or country recognized by the United States that enacts legislation allowing patients to purchase, at minimum, cannabis or cannabis products containing 5,000 mg of THC per month, except jurisdictions that limit the medical use of cannabis to hemp, as defined in SDCL 38-35-1, and its derivatives.

Source: __

General Authority: SDCL 34-20G-72(8)

Law Implemented: SDCL 34-20G-1(19)

44:90:02:09. Nonresident registration – Identification number.

1. The department shall issue to a nonresident cardholder who has met all registration requirements a nonrenewable 10-digit identification number, which shall expire on the earliest of:

(A) Six months from the date of issuance of the identification number;

(B) The expiration date of the nonresident's proof of authorization issued by the jurisdiction where the nonresident cardholder resides; or

(C) Any earlier expiration date specified by the practitioner's statement.

DOH DRAFT RULES

2. The registration number shall be valid at no more than two dispensaries, which shall be designated by the nonresident cardholder at the time of registration.

Source: __

General Authority: SDCL 34-20G-72(8)

Law Implemented: SDCL 34-20G-1(19)

44:90:02:10. Allowable quantity of cannabis products.

1. Under SDCL 34-20G-1(1)(b), cardholders and nonresident cardholders may possess a quantity of cannabis products with an equivalent cannabis weight totaling 3 ounces minus the amount of cannabis flower and trim possessed pursuant to SDCL 34-20G-1(1)(a).
2. The equivalent cannabis weight of cannabis products shall be:

Type of cannabis	**Amount equivalent to one ounce of cannabis**
Concentrated cannabis	8,000 mg
Vaporizer pens or cartridges	8,000 mg
Edibles (including tinctures, oils, or beverages tested by a certified testing facility)	80 servings providing 10 mg of THC
Tinctures, oils, or beverages (untested)	30 milliliters/1 fluid ounce
Topical (ointment or cream)	12 fluid ounces
Transdermal patches (tested)	80 doses of 10 mg THC
Transdermal patches (untested)	12 patches

Source: __

General Authority: SDCL 34-20G-72(9)

Law Implemented: SDCL 34-20G-1(1)(b), 34-20G-2, and 34-20G-3

44:90:02:11. Fees for registry identification cards.

DOH DRAFT RULES

1. The base fee for initial application and yearly renewal of a patient registry identification card for a resident of South Dakota shall be:

   (A) $20 for a low-income qualifying patient; and

   (B) $100 for all other applicants.

2. Qualifying patients shall submit an additional $20 fee for the issuance of any caregiver registry identification card, except no fee shall be charged for the designation of a caregiver at the time of the initial or renewal application.
3. An additional $20 fee is required for the printing of a two-part registry identification card for patients electing to cultivate cannabis or designate a caregiver to cultivate cannabis.
4. Nonresidents shall submit a $100 fee with a registration application.
5. All fees imposed under this section shall be nonrefundable.

Source: __

General Authority: SDCL 34-20G-72(10)

Law Implemented: SDCL 34-20G-29, 34-20G-31, 34-20G-3

DOH DRAFT RULES

CHAPTER 44:90:03

REGISTRATION CERTIFICATES

Section

44:90:03:01	Application for registration certificate – Components of complete application.
44:90:03:02	Operating procedures – Required contents – All medical cannabis establishments.

44:90:03:03 Cannabis cultivation facility operating procedures – Additional requirements.

44:90:03:04 Cannabis testing facility operating procedures – Additional requirements.

44:90:03:05 Cannabis product manufacturing facility operating procedures – Additional requirements.

44:90:03:06 Cannabis dispensary operating procedures – Additional requirements.

44:90:03:07 Compliance with local zoning requirements – Form of certification.

44:90:03:08 Local registration, license, or permit – Department verification.

44:90:03:09 No registration certificate revocation – Department verification.

44:90:03:10 No disqualifying felonies – Form of certification.

44:90:03:11 Department review of competitive application – Scoring criteria.

44:90:03:12 Department notification of applicants – Tiebreaking procedures.

44:90:03:13 Fees for registration certificate – Application and renewal – Change in location or ownership.

DOH DRAFT RULES

44:90:03:01. Application for registration certificate – Components of complete application.

1. An initial application for a registration certificate for any type of medical cannabis establishment shall include:

   (A) A completed application form;

   (B) Operating procedures consistent with this article;

   (C) Proof of property owner's consent to cultivation or manufacturing;

   (D) Certification of compliance from the local municipality or county ensuring applicant's proposed plans and location meet all local zoning and ordinance requirements;

   (E) Copies of all required registrations, licenses, or permits;

(F) Photocopies of a valid form of identification issued in South Dakota, or its equivalent issued in another U.S. jurisdiction, for all principal officers and board members;

(G) Photocopies of organizing documents, operating agreements, management agreements, bylaws, or other legal documents relating to the applicant's business structure;

(H) Certification that background checks have been completed for all medical cannabis establishment agents; and

(I) The applicable fee.

2. A renewal application for a registration certificate:

(A) Is required every 12 months or whenever 50 percent or more of the ownership interest in the establishment has been transferred since the most recent renewal application; and

(B) Shall include all components of an initial application, except that a detailed description of any changes to operating procedures, or a certification that no such changes exist, may be substituted for a complete set of operating procedures.

3. An application for the transfer of a registration certificate to a different physical location shall include:

(A) A completed change of location form;

(B) Diagrams of all locations in which cannabis will be cultivated, harvested, dried, stored, manufactured, or destroyed;

(C) A detailed description of any changes to operating procedures, or a certification that no such changes exist;

(D) Certification of compliance with all local zoning requirements;

(E) Copies of all required registration, licenses, or permits reflecting the establishment's new address; and

DOH DRAFT RULES

(F) The applicable fee.

4. An application to transfer less than 50 percent of the ownership interest in a medical cannabis establishment shall include:

   (A) A completed transfer of ownership interest form;

   (B) Photocopies of a valid form of identification issued in South Dakota, or its equivalent issued in another U.S. jurisdiction, for any new principal officers and board members;

   (C) Certification that background checks have been completed for any new medical cannabis establishment agents; and

   (D) The applicable fee.

Source: _

General Authority: SDCL 34-20G-72(2)

Law Implemented: SDCL 34-20G-55(1)

44:90:03:02. Operating procedures – Required contents – All medical cannabis establishments.

The operating procedures of any medical cannabis establishment shall include:

1. A management plan identifying the individuals who will be in charge of day-to-day operations of the establishment, including compliance with this article and SDCL chapter 34-20G and their specific management roles;

2. A site plan, which shall:

   (A) Identify any areas in which cannabis will be cultivated, harvested, dried, stored, manufactured, tested, or destroyed;

   (B) Indicate the types of activities that will take place in those areas;

DOH DRAFT RULES

(C) Identify a means of legal ingress onto property from the closest maintained public right of way; and

(D) Provide sufficient detail for the Department to determine that the establishment is completely self-contained and does not have any access to any other cannabis establishment or other business, except by public right of way.

3. Operating days and hours;
4. A workplace safety plan consistent with 29 CFR Part 1910 (2020), covering personal protective equipment, hazard assessment, safe equipment operation, proper application of agricultural chemicals, ladder use, hazard communication and other state and federal workplace safety requirements;
5. Plans for compliance with all applicable safety standards contained in local ordinance, SDCL chapter 11-10, ARSD article 61:15, and ARSD chapter 20:44:22;
6. A security plan indicating all doors, windows, gates, exterior lights, alarm sensors, cameras, and how alarms and cameras will be monitored;
7. Any additional steps to ensure the safety of patrons and the community;
8. Plans for preventing the diversion of cannabis to non-cardholders;
9. A waste management plan for disposal of cannabis waste and, if applicable, wastewater that conforms to federal, state, or local rules, regulations, and laws;
10. Pre-employment screening procedures, including criminal background check; and
11. Processes for limiting access by unauthorized persons, including verification of identity for all vendors and contractors, issuance of a visitor badge, and closely monitoring all visitors.

Source: _
General Authority: SDCL 34-20G-72(2) and 34-20G-72(3)

Law Implemented: SDCL 34-20G-55(1)(c)

DOH DRAFT RULES

44:90:03:03. Cannabis cultivation facility operating procedures – Additional requirements.

The operating procedures for a cultivation facility shall provide the Department with sufficient detail to determine the establishment's compliance with this article and SDCL chapter 34-20G, including:

1. Plans to obtain an adequate supply of cannabis seeds or seedlings;
2. The number of mature cannabis plants, or size of plant canopy, to be cultivated;
3. The number of seedlings to be cultivated;
4. Plans for wastewater and waste disposal for the cultivation facility and the applicant's certification of compliance with all state and federal laws;
5. The lights, irrigation, greenhouses and other equipment to be used and the approval listing;
6. Plans for providing electricity, water and other utilities necessary for the normal operation of the cultivation facility;
7. Plans for ventilation and filtration systems that reduce the potential for mold; and
8. A list of all pesticides, fungicides, insecticides, and fertilizers that will be present or used.

Source: _

General Authority: SDCL 34-20G-72(2)

Law Implemented: SDCL 34-20G-55(1)(c)

44:90:03:04. Cannabis testing facility operating procedures – Additional requirements.

DOH DRAFT RULES

The written operating procedures for a testing facility shall provide the Department with sufficient detail to determine the establishment's compliance with this article and SDCL chapter 34-20G, including without limitation:

1. A policy that, as indicated by signature, ensures management and personnel are free from any undue internal and external commercial, financial, or other influences that may adversely affect the quality of their work or diminish confidence in its competence, impartiality, judgement, or operational integrity;
2. A signed disclosure by the owner(s) stating that there is no financial conflict with, interest in, investment in, landlord-tenant relationship with or loan to a cannabis cultivation facility, cannabis product manufacturing facility, or cannabis dispensary;
3. A quality control and quality assurance manual;
4. A list of analytical tests, specifying the analyte and technology for each, the applicant intends to offer and:
   (A) Prior to July 1, 2024, proof that the applicant is working with an accreditation body to ensure compliance with applicable rules and ensure progress towards achieving ISO/IEC 17025 accreditation including all proposed analytical tests within its scope of accreditation; or
   (B) On or after July 1, 2024, proof of ISO/IEC 17025 accreditation for each analytical test proposed;
5. Standard operating procedures for all preanalytical, analytical, and post-analytical processes performed by the laboratory;
6. Protocols for performing validation studies of all analytical tests to be performed;

DOH DRAFT RULES

7. Protocols for biannual proficiency testing and documenting successful completion of above 80 percent;
8. A program to assess and document, at least annually, the competency of all technical and scientific staff that perform preanalytical, analytical, and postanalytical processes;
9. Policies and procedures that ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;
10. Policies and procedures for collection and receipt of samples for mandatory or other testing;
11. Chain of custody protocols and a sample chain of custody form; and
12. Equipment to be used and its listing by a nationally recognized testing laboratory.

Source: _

General Authority: SDCL 34-20G-72(2)

Law Implemented: SDCL 34-20G-55(1)(c)

Reference: International Organization for Standardization & International Electrotechnical Commission. (2018). *ISO/IEC 17025:2017: General Requirements for the Competence of Testing and Calibration Laboratories.* https://www.iso.org/standard/66912.html

44:90:03:05. Cannabis product manufacturing facility operating procedures – Additional requirements.

The operating procedures for a cannabis product manufacturing facility shall provide the department with sufficient detail to determine the establishment's compliance with this article and SDCL chapter 34-20G, including:

DOH DRAFT RULES

1. A description of the classes of products, such as extracts, inhaled products, edible products, beverages, topical products, ointments, oils, and tinctures, that will be manufactured by the establishment;
2. A detailed description of the manufacturing processes that will occur on the premises, including:
   (A) Mechanical extraction using potable water, ice, dry screening or sieving, cryonic extraction, pressure, or temperature;
   (B) Infusion into propylene glycol, glycerin, or food-grade fats;
   (C) Extraction using food-grade ethanol; and
   (D) Extraction using an inherently hazardous substance;
3. A diagram illustrating in which areas of the premises each manufacturing activity will occur;
4. A diagram illustrating the areas of the premises where any solvent, excluding water, chemical or potentially hazardous substance will be stored;
5. Plans for ventilation and filtration systems that reduce the risk of fire or respiratory harm within the facility;
6. Certification from a professional engineer licensed in this state of the safety of the equipment used for cannabis extraction and the location of the equipment and the professional engineer's approval of the standard operating procedures for the cannabis extraction;
7. Documentation from a professional engineer licensed in this State or a state or local official authorized to certify compliance that the equipment used for cannabis extraction and the location of the equipment comply with all applicable safety standards contained in local ordinance, SDCL chapter 11-10, ARSD article 61:15, and ARSD chapter 20:44:22; and

DOH DRAFT RULES

8. Documentation from the manufacturer of the cannabis extraction system or a professional engineer licensed in this State showing that a professional grade, closed-loop extraction system that recovers the solvents used to produce cannabis extract is used by the establishment.

Source: _

General Authority: SDCL 34-20G-72(2)

Law Implemented: SDCL 34-20G-55(1)(c)

44:90:03:06. Cannabis dispensary operating procedures – Additional requirements.

The operating procedures for a dispensary shall provide the department with sufficient detail to determine the establishment's compliance with this article and SDCL chapter 34-20G, including:

1. Plans to obtain an adequate supply of cannabis, cannabis extracts, and cannabis products;
2. Types of products offered;
3. Verification of identification card and purchase limits;
4. Advertising plan, including onsite signs;
5. Training plan;
6. Point-of-sale software to be used, including documentation of its interoperability with the inventory tracking system;
7. Parking;
8. Accessibility to individuals with disabilities; and
9. Suitability of location for maximizing access by cardholders.

Source: _

General Authority: SDCL 34-20G-72(2) and 34-20G-72(3)

DOH DRAFT RULES

Law Implemented: SDCL 34-20G-55(1)(c)

44:90:03:07. Compliance with local zoning requirements – Form of certification.

Each initial or renewal application shall include the application's certification, on a form supplied by the department, of compliance with all applicable city and county zoning requirements, including any city or county odor ordinances or regulations.

Source: _

General Authority: SDCL 34-20G-72(2)

Law Implemented: SDCL 34-20G-55(1)(d)

44:90:03:08. Local registration, license, or permit – Department verification.

1. Each initial or renewal application shall include either:
   (A) A certification, on a form supplied by the department, that the applicant is not required to obtain any city or county registration, license, or permit; or
   (B) Copies of all required registrations, licenses, or permits.
2. The department may contact the city or county to verify the absence of registration, licensing, or permitting requirements or to verify the form and content of such documents.

Source: _

General Authority: SDCL 34-20G-72(2)

Law Implemented: SDCL 34-20G-55(1)(e) and 34-20G-60

44:90:03:09. No registration certificate revocation – Department verification.

DOH DRAFT RULES

Each initial or renewal application shall include a certification, on a form supplied by the department, that none of the principal officers or board members has served as a principal officer or board member for a medical cannabis establishment that has had its registration certificate revoked.

Source: _

General Authority: SDCL 34-20G-72(2)

Law Implemented: SDCL 34-20G-55(2)

44:90:03:10. No disqualifying felonies – Form of certification.

With each initial or renewal application:

1. Each principal officer or board member shall aver that the individual has not been convicted of any violent felony offense in the previous 10 years, whether in South Dakota or another jurisdiction.
2. The signatory to the application shall aver that the applicant has conducted background checks on all principal officers and board members within 90 days of the initial application or within two years of a renewal application.

Source: _

General Authority: SDCL 34-20G-72(2)

Law Implemented: SDCL 34-20G-61 and 34-20G-62

44:90:03:11. Department review of competitive applications – Scoring criteria.

DOH DRAFT RULES

In cases where more applicants apply than are allowed by the local government, the department shall numerically score competitive applications according to the following criteria:

1. The city or county limiting the number of establishments, in response the department's inquiry, has endorsed the application as beneficial to the community (1 point).
2. The city or county limiting the number of establishments has not informed the department the location specified in the application is unsuitable, due to zoning regulations or inaccessibility to the public, for the proposed use (1 point).
3. All principal officers and board members have certified that they have not, in the previous 10 years, in any U.S. jurisdiction:
   (A) Been convicted of a criminal offense involving fraud or false statements to a unit of government (1 point); or
   (B) Served as a principal officer or board member of any business that has had a license or permit suspended or revoked for violations of laws or regulations relating to cannabis, alcohol, tobacco, or gaming (1 point).
4. The applicant has submitted a floorplan with sufficient detail to enable the department to determine where all activities listed in the operating procedures will take place (1 point).
5. The applicant has submitted a business plan outlining the details contained in SDCL 34-20G-72(3)(d) (1 point).

Source: _

General Authority: SDCL 34-20G-72(3)

Law Implemented: SDCL 34-20G-56

DOH DRAFT RULES

44:90:03:12. Department notification of applicants – Tiebreaking procedures.

1. The dispensary applicant with the highest score shall be awarded a registration certificate.
2. If the city or county has enacted an overall limit on the number of establishments, the department shall award registration certificates, in order of final score, until the limit is reached.
3. If the city or county has enacted a limit on establishments by establishment type, the department shall award registration certificates, in order of final score, until the limit is reached for each establishment type.
4. If applicants are tied for one or more openings in a locality, the affected applicants shall have the opportunity to view, in person or via videoconference, a random drawing to determine the successful applicants.
5. The notification of unsuccessful applicants shall identify the department's decision as a final department action subject to judicial review.

Source: _

General Authority: SDCL 34-20G-72(3)

Law Implemented: SDCL 34-20G-56 and 34-20G-59

44:90:03:13. Fees for registration certificates – Application and renewal – Change in location or ownership.

1. Applicants shall submit a $5,000 fee with an initial or renewal application for a registration certificate.
2. Establishments shall submit a $250 fee with an application to

   (A) Operate at a different physical location.

DOH DRAFT RULES

(B) Transfer an ownership interest to any person not listed on the establishment's most recent initial or renewal application.

3. Establishments shall submit a $50 fee with each request for an agent identification badge.
4. The fees imposed under this section shall increase annually based on the index factor.
5. The fees imposed under this section shall be nonrefundable.

Source: __

General Authority: SDCL 34-20G-72(10)

Law Implemented: SDCL 34-20G-55

DOH DRAFT RULES

CHAPTER 44:90:04

ESTABLISHMENTS

Section

44:90:04:01	Change in management – Duty to report.
44:90:04:02	Corrective and preventive action – Written procedures.
44:90:04:03	Duty to report criminal activity to department.
44:90:04:04	Duty to report criminal activity to law enforcement.
44:90:04:05	Lighting.
44:90:04:06	Doors and windows.
44:90:04:07	Placement of security cameras.
44:90:04:08	Recording by security cameras – Access by department.
44:90:04:09	Storage of camera footage.
44:90:04:10	Alarm system.
44:90:04:11	Notification to department.

44:90:04:12 Agent identification badges to be obtained by establishments.

44:90:04:13 Agent identification badges to be displayed.

44:90:04:14 Controlled access – Verification of identity.

44:90:04:15 Visitor badges to be worn by contractors performing work at a medical cannabis establishment.

44:90:04:16 Operation of agricultural, industrial, or other heavy equipment – Training requirements.

44:90:04:17 Record-keeping -- Use of inventory tracking system– Training requirements.

44:90:04:18 Security protocols– Training requirements.

44:90:04:19 Vehicle requirements – Establishments.

44:90:04:20 Transport manifests – Form and content.

44:90:04:21 Storage during transport.

44:90:04:22 Conduct during transport.

44:90:04:23 Transport incident notification.

44:90:04:24 Health and safety standards for storage.

44:90:04:25 Storage while awaiting test results.

44:90:04:01. Change in management – Duty to report.

An establishment shall remain under the direction of the individuals identified in its management plan and shall provide the department an updated management plan within seven days after any change in management personnel occurs.

Source: __

General Authority: SDCL 34-20G-72(5)(a)

Law Implemented: SDCL 34-20G-63

44:90:04:02. Corrective and preventive action – Written procedures.

DOH DRAFT RULES

An establishment shall maintain and follow written procedures for implementing corrective action and preventive action, including:

1. Analysis of processes, work operations, reports, records, service records, complaints, returned product, and other sources of data to identify existing and potential root causes of nonconformance or other quality problems;
2. Identifying any actions needed to correct and prevent recurrence of nonconformance and other quality problems;
3. Verifying the corrective action or preventive action to ensure that such action is effective and does not adversely affect finished products or processes;
4. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
5. Ensuring the information related to quality problems or nonconformance is disseminated to those directly responsible for assuring the quality of products or the prevention of such problems;
6. Submitting relevant information on identified quality problems and corrective action and preventive action documentation, and confirming the result of the evaluation, for management review; and
7. Ensuring that cannabis or cannabis products that do not meet safety standards are quickly identified and destroyed or remediated to prevent harm to patients.

Source: __

General Authority: SDCL 34-20G-72(5)(a)

Law Implemented: SDCL 34-20G-63, 34-20G-71

DOH DRAFT RULES

44:90:04:03. Duty to report criminal activity to department.

In addition to notice required by SDCL 34-20G-50, an establishment shall provide notice to the department within one business day upon its discovery of any plan or other action of any person to:

1. Steal cannabis plants, cannabis, cannabis products, cannabis paraphernalia, equipment, or money;
2. Sell or otherwise provide cannabis plants, cannabis, cannabis products, or cannabis paraphernalia to unauthorized persons;
3. Purchase or otherwise obtain cannabis plants, cannabis, cannabis products, or cannabis paraphernalia by unauthorized persons;
4. Falsify inventory records or transport manifests; or
5. Commit any other crime relating to the operation of the establishment.

Source: __

General Authority: SDCL 34-20G-72(5)(a)

Law Implemented: SDCL 34-20G-50, 34-20G-63, and 34-20G-64

44:90:04:04. Duty to report criminal activity to law enforcement.

Any criminal activity reported to the department shall also be reported to a local law enforcement agency.

Source: __

General Authority: SDCL 34-20G-72(5)(a)

Law Implemented: SDCL 34-20G-63 and 34-20G-88

DOH DRAFT RULES

44:90:04:05. Lighting.

(1) Any gate or perimeter entry point of a medical cannabis establishment must have lighting sufficient for observers to see, and cameras to record, any activity within ten feet of the gate or entry.

(2) A motion detection lighting system may be employed to light required areas in low-light conditions.

Source: __
General Authority: SDCL 34-20G-72(5)(c)
Law Implemented: SDCL 34-20G-64

44:90:04:06. Doors and windows.

Commercial grade locks, intended for facilities requiring high levels of physical security, are required on all perimeter entry doors. All windows must be in good condition and lockable.

Source: __
General Authority: SDCL 34-20G-72(5)(c)
Law Implemented: SDCL 34-20G-64

44:90:04:07. Placement of security cameras.

All establishments must permanently fix security cameras:

1. At each exterior door and gate to allow identification of persons entering or exiting the premises.

DOH DRAFT RULES

2. At each door separating non-public areas of a dispensary from areas in which sales to patients and caregivers are made, to allow identification of persons entering or exiting non-public areas.
3. In sufficient number to allow the viewing, in its entirety, of any area where cannabis, cannabis plants, cannabis products, or cannabis waste are cultivated, manufactured, stored, destroyed, disposed, or prepared for transfer, sale, or testing.

Source: __

General Authority: SDCL 34-20G-72(5)(c)

Law Implemented: SDCL 34-20G-64

44:90:04:08. Recording by security cameras – Access by department.

1. Video surveillance shall meet the following minimum requirements:
   (A) Minimum resolution of 720 pixels;
   (B) Internet protocol (IP) compatibility supporting live viewing by the department over a secure internet connection;
   (C) Minimum of 15 frames per second; and
   (D) Clear and accurate display of time and date.
2. The cameras shall be set to record 24 hours a day at all establishments, except cameras placed at exterior doors used by patients to enter or exit the dispensary, which to ensure patient privacy shall be set to record only outside of the dispensary's operating hours.
3. Surveillance systems shall have a backup power source allowing for recording and transmitting video for a minimum of two hours in the event of a power failure.

Source: __

DOH DRAFT RULES

General Authority: SDCL 34-20G-72(5)(c)

Law Implemented: SDCL 34-20G-64

44:90:04:09. Storage of camera footage.

1. An establishment must maintain surveillance recordings for a minimum of 180 days, either:
   (A) On a surveillance system storage device secured on the premises in a lockbox, cabinet, or closet and alarmed with motion and seismic sensors to protect from employee tampering or criminal theft; or
   (B) Stored on a secure third-party server.
2. All video recordings are subject to inspection by any department employee or law enforcement officer and must be copied and provided to the department or law enforcement officer upon request.
3. Licensees must maintain a list of all persons with access to video surveillance recording and written procedures for controlling access to recordings.

Source: __

General Authority: SDCL 34-20G-72(5)(c)

Law Implemented: SDCL 34-20G-64

44:90:04:10. Alarm system.

1. Monitored sensors are required on all exterior doors, windows, and gates.
2. Alarm systems must be monitored by a security company capable of contacting the establishment and, if necessary, law enforcement.

DOH DRAFT RULES

3. The system must include an audible alarm, which must be capable of being disabled remotely by the security company.
4. Surveillance systems shall alert the security company in the event of a power failure and shall operate for a minimum of four hours on backup power.

Source: __

General Authority: SDCL 34-20G-72(__)

Law Implemented: SDCL 34-20G-__

44:90:04:11. Notification to department.

An establishment must notify local law enforcement and the department within 24 hours upon learning of any unauthorized entry or theft of cannabis, cannabis plants, or cannabis products.

Source: __

General Authority: SDCL 34-20G-72(5)(c)

Law Implemented: SDCL 34-20G-50

44:90:04:12. Agent identification badges to be obtained by establishments.

1. A medical cannabis establishment must obtain an agent identification badge for any agent before that person is permitted to perform duties on the site of the establishment or transport cannabis, cannabis extracts, or cannabis products.
2. The application for an agent identification badge shall be made on a form supplied by the department, which shall include an attestation that the establishment has obtained a criminal background check on the applicant in the previous two years, and which shall be

DOH DRAFT RULES

accompanied by a photograph meeting the requirements for a United States passport and the required fee.

3. The identification badge shall remain the property of the department.
4. An establishment must inform the department immediately if the individual ceases to be an agent of the establishment. The badge shall become void and shall be returned to the department.

Source: __

General Authority: SDCL 34-20G-72(5)(g)

Law Implemented: SDCL 34-20G-72(5)(g)

44:90:04:13. Agent identification badges to be displayed.

A medical cannabis establishment must provide a department-issued agent identification badge to each agent, who must display this badge whenever on the premises of the establishment or transporting cannabis, cannabis extract, or cannabis products.

Source: __

General Authority: SDCL 34-20G-72(5)(g)

Law Implemented: SDCL 34-20G-72(5)(g)

44:90:04:14. Controlled access – Verification of identity.

1. No medical cannabis establishment shall share premises with or permit access directly from another medical cannabis establishment, business that sells alcohol or tobacco, or, if allowed by law, other cannabis establishment.

DOH DRAFT RULES

2. A medical cannabis establishment must verify the age and identity of anyone entering the premises.
3. Unless permitted by ARSD 44:90:08:01, no person shall be allowed to enter the premises other than agents of the establishment, cardholders, contractors 21 years of age or older hired by the establishment, employees or agents of the department, law enforcement officers, employees or agents of other local or state agencies with regulatory authority, including fire marshals, electrical inspectors, pesticide control staff and environmental inspectors, for the purpose of exercising such regulatory authority.

Source: __

General Authority: SDCL 34-20G-72(5)(g)

Law Implemented: SDCL 34-20G-65

44:90:04:15. Visitor badges to be worn by contractors performing work at a medical cannabis establishment.

A medical cannabis establishment must issue a visitor badge to any temporary contractor of the establishment whose scope of work will not involve the handling of cannabis, cannabis plants, cannabis extracts, or cannabis products, including a carpenter, electrician, plumber, engineer, or alarm technician. Such contractors shall work under the direct supervision of a medical cannabis establishment agent whenever working in an area in which cannabis plants, cannabis, cannabis extracts, or cannabis products are present.

Source: __

General Authority: SDCL 34-20G-72(5)(g)

Law Implemented: SDCL 34-20G-65

DOH DRAFT RULES

44:90:04:16. Operation of agricultural, industrial, or other heavy equipment – Training requirements.

1. Establishment agents shall receive thorough training in the safe operation of any heavy agricultural equipment, industrial equipment such as extraction and packaging equipment, and other heavy equipment such as forklifts, before operating such equipment.
2. Establishment agents shall complete OSHA-approved certification courses prior to using any equipment if required under local ordinance or state law.

Source: __

General Authority: SDCL 34-20G-72(5)(g)

Law Implemented: SDCL 34-20G-72(5)(g)

44:90:04:17. Record-keeping – Use of inventory tracking system – Training requirements.

1. Prior to performing duties onsite or transporting cannabis, an establishment agent shall receive at minimum two hours of training in record keeping, which shall be documented in the establishment's records.
2. Any establishment agent who will enter data into the inventory tracking system required by the department shall additionally receive at minimum two hours of hands-on training; and
3. At least one establishment agent shall receive at minimum four hours of training to act as an administrator of the inventory tracking system.

Source: __

General Authority: SDCL 34-20G-72(g)

Law Implemented: SDCL 34-20G-__

DOH DRAFT RULES

44:90:04:18. Security protocols– Training requirements.

Each establishment agent shall receive training in all aspects of the establishment's security protocol, focusing on the agent's role in deterring and preventing theft and preventing unauthorized access to the premises.

Source: __

General Authority: SDCL 34-20G-72(5)(g)

Law Implemented: SDCL 34-20G-64

44:90:04:19. Vehicle requirements – Establishments.

Establishments must provide the following information to the department for each vehicle that will be used to transport cannabis, cannabis concentrate, or cannabis products, including samples for testing:

1. Make, model, and license plate number;
2. Proof of a valid insurance policy;
3. A description, with photos as necessary, of a locking compartment to be used to secure cannabis, cannabis extracts, and cannabis products;
4. Verification that the vehicle has a functioning alarm system; and
5. A description of how the cannabis, cannabis extracts, or cannabis products will be maintained in an appropriate temperature range.

Source: __

General Authority: SDCL 34-20G-72(5)(f)

Law Implemented: SDCL 34-20G-8, 34-20G-9, 34-20G-10, and 34-20G-11

DOH DRAFT RULES

44:90:04:20. Transport manifests – Form and content.

1. A transport manifest is required for all authorized transfers of any amount of cannabis, cannabis extracts, or cannabis products, except retail sales at a dispensary.
2. The transport manifest shall contain:
   (A) The name, address, phone number, and license number of the establishment transporting the cannabis, cannabis extracts, or cannabis products;
   (B) The name, address, phone number, and license number of the establishment receiving the items;
   (C) The phone number and web address of the department's secure verification system;
   (D) Description and quantities, either by weight or unit, of all items, including samples, contained in each transport;
   (E) Date of transport and approximate time of departure and arrival;
   (F) Vehicle make, model and license plate number;
   (G) The name and signature of driver and any other agent accompanying the transport; and
   (H) The name and signature of the person accepting the transport, upon delivery.
3. A separate transport manifest must be prepared for each medical cannabis establishment that will receive cannabis, cannabis extracts, or cannabis products.
4. The vehicle must carry three copies of each transport manifest:
   (A) One for the recipient;
   (B) One to be returned to the originating establishment for the purposes of record keeping; and

DOH DRAFT RULES

(C) One to be provided at the request of law enforcement or an agent of the department, if the vehicle is involved in a traffic stop or collision.

5. Any cannabis, cannabis products, or cannabis extracts, including samples, that are refused by the intended recipient shall be noted on the transport manifest and noted in the establishments inventory records after the items are returned.
6. A transport manifest shall not otherwise be altered after departing from the originating premises.
7. The transport manifest does not take the place of a chain-of-custody form that may be required of the establishment.

Source: __

General Authority: SDCL 34-20G-72(5)(f)

Law Implemented: SDCL 34-20G-8, 34-20G-9, 34-20G-10, and 34-20G-11

44:90:04:21. Storage during transport.

1. All cannabis or cannabis products being transported must be contained within an enclosed, locked area in the transport vehicle and out of public view.
2. Samples of cannabis, cannabis extracts, and cannabis products for testing shall be transported in appropriately labeled sample collection containers with tamper evident seals affixed.
3. All cannabis, cannabis extracts, or cannabis products being transported to another establishment, other than samples for testing, shall be transported within sealed containers identifying the recipient.
4. A cannabis product manufacturing facility or dispensary transporting any edible product requiring refrigeration to another establishment must provide refrigerated transport.

DOH DRAFT RULES

Source: __

General Authority: SDCL 34-20G-72(5)(f)

Law Implemented: SDCL 34-20G-8, 34-20G-9, 34-20G-10, and 34-20G-11

44:90:04:22. Conduct during transport.

1. Only agents of the establishment, wearing agent identification badges, and who are listed on each transport manifest, may be in the vehicle.
2. Any vehicle transporting cannabis, cannabis extract, or cannabis products must travel directly to the destinations listed on transport manifests, making stops only:
   (A) For meals, when the transport lasts more than three hours round trip;
   (B) For rest periods required by law;
   (C) To refuel; or
   (D) Under exigent circumstances, including collisions, traffic stops, mechanical breakdowns, weather emergencies, or medical emergencies.
3. The agents may not remove the cannabis, cannabis extracts, or cannabis products from the vehicle until arrival at the destination listed on the transport manifest, except under exigent circumstances in consultation with the department.
4. An establishment agent must make a vehicle used for the transport of cannabis, cannabis extract, or cannabis products immediately available for inspection upon request of the department.
5. Upon law enforcement stop or other contact all persons in the vehicle shall identify themselves with their agent identification badges and all transport manifests.

Source: __

DOH DRAFT RULES

General Authority: SDCL 34-20G-72(5)(f)

Law Implemented: SDCL 34-20G-8, 34-20G-9, 34-20G-10, and 34-20G-11

44:90:04:23. Transport incident notification.

1. Any traffic stop, breakdown, or collision involving a vehicle being used by an establishment to transport cannabis, cannabis extract, or cannabis products, or any unscheduled stop lasting more than two hours shall be reported to the department within one business day.
2. Any theft or break-in involving a vehicle being used by an establishment to transport cannabis, cannabis extract, or cannabis products shall be reported to local law enforcement immediately and to the department within one business day.
3. If exigent circumstances require removal of cannabis from the vehicle prior to arrival at the destination listed on the transport manifest, the establishment agents shall make a good faith effort to contact the department for direction. If unable to contact the department, the establishment agents shall make good faith efforts to protect the shipment from diversion.

Source: __

General Authority: SDCL 34-20G-72(5)(f)

Law Implemented: SDCL 34-20G-8, 34-20G-9, 34-20G-10, and 34-20G-11

44:90:04:24. Health and safety standards for storage.

A medical cannabis establishment shall store cannabis, and cannabis products, unless on display for sale:

1. In secure, sealed containers that prevent against damage from light, water, insects, or rodents; and

DOH DRAFT RULES

2. Under environmental conditions, including refrigeration of any perishable edible product, that will protect against physical, chemical, or microbial contamination and damage from temperature or humidity.

Source: __

General Authority: SDCL 34-20G-72(5)(f)

Law Implemented: SDCL 34-20G-8, 34-20G-9, 34-20G-10, and 34-20G-11

44:90:04:25. Storage while awaiting test results.

A cultivation facility or cannabis product manufacturing facility awaiting testing results must:

1. Enter the identification number of the batch and the identification number of the samples associated with the batch into the establishment's inventory records;
2. Store the batch in one or more sealed containers enclosed on all sides; and
3. Affix to the container(s) a label including the following information:
   (A) The establishment's identification number;
   (B) The batch number entered into inventory records;
   (C) Name and identification number of the testing facility that will perform the tests;
   (D) The sample's unique identification number
   (E) The date the samples were taken; and
   (F) In bold, capital letters, no smaller than 12-point font, "PRODUCT NOT TESTED"

Source: __

General Authority: SDCL 34-20G-72(5)(f)

Law Implemented: SDCL 34-20G-8, 34-20G-9, 34-20G-10, and 34-20G-11

DOH DRAFT RULES

CHAPTER 44:90:05

CANNABIS CULTIVATION FACILITIES

Section

44:90:05:01	Cultivation activities – Compliance with operating procedures.
44:90:05:02	Packaging and labeling cannabis for retail sale.
44:90:05:03	Cultivation equipment - Safety.
44:90:05:04	Cultivation area.
44:90:05:05	Hours of operation – Exigent circumstances.
44:90:05:06	Fences and greenhouses.
44:90:05:07	Safe application of pesticides and other chemicals used in cultivation– Training requirements.
44:90:05:08	Application of pesticides.
44:90:05:09	List of approved active ingredients in pesticides.
44:90:05:10	Safety of cannabis -- Use or presence of prohibited pesticides – Contaminants.

44:90:05:01. Cultivation activities – Compliance with operating procedures.

A cultivation facility must have onsite, whenever establishment agents are present, a principal officer or other manager with responsibility for ensuring that all activities comply with the establishment's operating procedures, including:

1. Propagating and cultivating cannabis plants;
2. Trimming, drying, curing, and storing cannabis;
3. Packaging cannabis, including testing samples;
4. Transporting cannabis to another establishment, including testing samples; and

DOH DRAFT RULES

5. Maintaining all required records.

Source: __

General Authority: SDCL 34-20G-72(5)(e)

Law Implemented: SDCL 34-20G-9

44:90:05:02. Packaging and labeling cannabis for retail sale.

A cultivation facility may package and label for retail sale in packages of three ounces or less:

1. Cannabis flower and trim; and
2. Pre-rolled cannabis cigarettes, containing only cannabis flower or trim and an unflavored paper wrapper.

Source: __

General Authority: SDCL 34-20G-72(5)(e)

Law Implemented: SDCL 34-20G-9

44:90:05:03. Cultivation equipment - Safety.

All electrical equipment, including but not limited to growing lights, cultivation equipment and packaging equipment, must be listed by a nationally recognized testing laboratory.

Source: __

General Authority: SDCL 34-20G-72(5)(e)

Law Implemented: SDCL 34-20G-9

44:90:05:04. Cultivation area.

DOH DRAFT RULES

Any cultivation of seedlings, immature plants, or mature plants must take place in:

1. An indoor facility meeting all security requirements of this article;
2. One or more greenhouses meeting all security requirements of an indoor facility; or
3. Within a secured fenced in area meeting all security requirements, either outdoors or in greenhouses not meeting security requirements.

Source: __

General Authority: SDCL 34-20G-72(5)(e)

Law Implemented: SDCL 34-20G-9

44:90:05:05. Hours of operation – Exigent circumstances.

Agents of a cultivation facility may not, outside of the hours of operation stated on the operating plan of record, plant, feed, water, treat, move, harvest, dry, cure, package, destroy, or dispose cannabis, except:

1. Under exigent circumstances in which prompt action is necessary to protect inventory from destruction; and
2. With notice to the department within one business day regarding the character of the emergent circumstances, the activities to be conducted and the hours during which such activities will occur.

Source: __

General Authority: SDCL 34-20G-72(5)(e)

Law Implemented: SDCL 34-20G-9

44:90:05:06. Fences and greenhouses.

DOH DRAFT RULES

1. Any cultivation facility cultivating, processing, or storing cannabis outdoors or in greenhouses or other structures that do not meet all security requirements for buildings must secure such cultivation areas with fencing and lighting.
2. Fencing and all gates must be secure, at least six feet high and obscure, or have a cover that obscures, regulated activities from being readily viewed from outside of the fenced in area.

Source: __

General Authority: SDCL 34-20G-72(5)(c)

Law Implemented: SDCL 34-20G-64

44:90:05:07. Safe application of pesticides and other chemicals used in cultivation– Training requirements.

1. Any establishment agent who applies a department-approved fungicide, insecticide, or rodenticide shall hold a current pesticide applicator certification issued by the South Dakota Department of Agriculture and Natural Resources pursuant to ARSD chapter 12:56:05.
2. Any establishment agent who applies or uses other agricultural chemicals shall have training in their safe use, including mitigating any risks to humans, animals, or waterways.

Source: __

General Authority: SDCL 34-20G-72(5)(d)

Law Implemented: SDCL 34-20G-72(5)(d)

44:90:05:08. Application of pesticides.

1. The use of a pesticide in the cultivation of cannabis is prohibited unless it:

   (A) Is listed in the cultivation facility's operating procedures filed with the department; and

DOH DRAFT RULES

(B) Contains only those active ingredients approved by the department pursuant to ARSD section 44:90:05:11 of this article.

2. An approved pesticide shall be applied only by an establishment agent with a current pesticide applicator license and only in a manner consistent with the label.

Source: __

General Authority: SDCL 34-20G-72(5)(d)

Law Implemented: SDCL 34-20G-9 and 34-20G-11

44:90:05:09. List of approved active ingredients in pesticides.

1. The following synthetic chemical agents are approved as active ingredients in pesticides when used in a manner consistent with the label:

(A) Auxin;

(B) Azadirachtin;

(C) Capric acid;

(D) Caprylic acid;

(E) Citric acid;

(F) Copper octoanoate;

(G) Cytokinins;

(H) Diatomaceous earth;

(I) Gibberellic acid;

(J) Horticultural oils;

(K) Hydrogen peroxide;

(L) Indole-3-butyric acid;

DOH DRAFT RULES

(M) Insecticidal soaps;

(N) Iron phosphate;

(O) Methoprene;

(P) Peroxyacetic acid;

(Q) Petroleum oils;

(R) Phosphorous acid, including salts thereof;

(S) Potassium bicarbonate;

(T) Potassium silicate;

(U) Potassium sorbate;

(V) Sodium bicarbonate;

(W) Sodium ferric EDTA;

(X) Sodium laurel sulfate; and

(Y) Sulfur.

2. The following bacterial or fungal agents are approved as active ingredients in pesticides when used in a manner consistent with the label:

(A) Bacillus amyloliquefaciens strain D747;

(B) Bacillus subtilis QST;

(C) Bacillus thuringiensis;

(D) Beauveria bassianaa;

(E) Burkholderia spp. Strain A396;

(F) Gliocladium virens;

(G) Harpin alpha beta;

(H) Isaria fumosorosea;

DOH DRAFT RULES

(I) Myrothecium verrucaria;

(J) Reynoutria sachalinensis;

(K) Trichoderma asperellum strain T34; and

(L) Trichoderma harzianum.

3. The following plant extracts are approved as active ingredients in pesticides when used in a manner consistent with the product label:

(A) Capsaicin;

(B) Castor oil;

(C) Cinnamon oil;

(D) Clove oil;

(E) Corn oil;

(F) Cottonseed oil;

(G) Garlic oil;

(H) Geraniol;

(I) Geranium oil;

(J) Lemongrass oil;

(K) Linseed oil;

(L) Neem oil;

(M) Olive oil;

(N) Peppermint oil;

(O) Pyrethrins;

(P) Rosemary oil;

(Q) Sesame oil;

DOH DRAFT RULES

(R) Soybean oil; and

(S) Thyme oil.

Source: __

General Authority: SDCL 34-20G-72(5)(d)

Law Implemented: SDCL 34-20G-9

44:90:05:10. Safety of cannabis -- Use or presence of prohibited pesticides – Contaminants.

1. The use or presence at a medical cannabis establishment of any pesticide listing an active ingredient not on the approved list shall be considered a violation of this article and SDCL chapter 34-20G.
2. The knowing use or presence at a medical cannabis establishment of any pesticide listing as an active ingredient a synthetic chemical agent not on the approved list shall be considered a serious violation of this article and SDCL chapter 34-20G.
3. The knowing use or presence at a medical cannabis establishment of any pesticide listing a nonsynthetic substance prohibited in organic crop production under 7 CFR section 205.602 (2021) shall be considered a serious violation of this article and SDCL chapter 34-20G.
4. Cannabis shall be considered non usable if it contains detectable levels of any of the following contaminants:

   (A) Residual pesticides unless approved by the department;

   (B) Residual solvents other than ethanol, glycerin, propylene glycol, or cooking fats;

   (C) Mold, yeast, or mycotoxins;

   (D) Coliform bacteria, enterobacteriaceae, e. coli, or salmonella; or

   (E) Cadmium, lead, arsenic, or mercury.

DOH DRAFT RULES

Source: __

General Authority: SDCL 34-20G-72(5)(d) and 34-20G-72(5)(e)

Law Implemented: SDCL 34-20G-9

CHAPTER 44:90:06

CANNABIS TESTING FACILITIES

Section

44:90:06:01 Required Accreditation and Registration – ISO/IEC 17025 – Drug Enforcement Agency.

44:90:06:02 Adherence to standard operating procedures – Quality control and quality assurance -- Sample collection.

44:90:06:03 Chain of custody protocols.

44:90:06:04 Mandatory testing for pesticides.

44:90:06:05 Testing of samples by State Public Health Laboratory or another laboratory.

44:90:06:01. Required Accreditation and Registration – ISO/IEC 17025 – Drug Enforcement Agency.

1. Prior to July 1, 2024, all cannabis testing facilities must work with an accreditation body to ensure compliance with applicable rules and ensure progress towards achieving ISO/IEC 17025 accreditation, with a scope of accreditation that includes all analytical tests performed by the facility.

DOH DRAFT RULES

2. On or after July 1, 2024, a cannabis testing facility may not accept cannabis or cannabis products for testing unless the facility is ISO/IEC accredited and the analytical tests to be performed are within the facility's scope of accreditation.
3. A cannabis testing facility shall be registered with the Drug Enforcement Agency pursuant to 21 CFR part 1301 (2019).

Source: __

General Authority: SDCL 34-20G-72(5)(k)

Law Implemented: SDCL 34-20G-11

Reference: International Organization for Standardization & International Electrotechnical Commission. (2018). *ISO/IEC 17025:2017: General Requirements for the Competence of Testing and Calibration Laboratories.* https://www.iso.org/standard/66912.html

44:90:06:02. Adherence to standard operating procedures – Quality control and quality assurance -- Sample collection.

1. A cannabis testing facility shall adhere to its operating procedures, including:
   (A) The written procedures for all preanalytical, analytical, and post-analytical processes
   (B) Its quality control and quality assurance manual;
   (C) Completion of validation studies of all analytical tests to be performed;
   (D) Proficiency testing at an interval defined by the accrediting body;
   (E) Achieves a passing score on each proficiency test, or in the event of a non-passing score, completes remediation as defined by the accrediting body; and
   (F) A program to assess and document, at least annually, the competency of all technical and scientific staff that perform preanalytical, analytical, and postanalytical processes.

DOH DRAFT RULES

2. Each cannabis testing facility shall adopt standard operating procedures for the collection of samples for testing, which shall address:

   (A) Minimum and maximum batch size for cannabis and cannabis products;

   (B) Standards for the assignment of batch identifiers and sample identifiers;

   (C) Minimum quantity of cannabis and cannabis products needed for each analytical test;

   (D) Methodology for collecting material that is representative of the entire batch being tested;

   (E) Cleaning, sanitizing, and other methods for preventing sample contamination;

   (F) Containers to be used for sample collection, including methods for sealing; and

   (G) Prevention of damage or degradation during storage and transport.

Source: __

General Authority: SDCL 34-20G-72(5)(k)

Law Implemented: SDCL 34-20G-11

44:90:06:03. Chain of custody protocols.

1. The chain of custody protocols developed by a cannabis testing facility shall be approved by the department and must address:

   (A) Recording the possession of samples from the time of sampling through destruction;

   (B) Retaining for not less than 90 days any residual samples in the container in which the sample was submitted;

   (C) Handling procedures during collection, transport, and testing to avoid loss, damage, diversion, contamination, or misidentification of samples; and

   (D) The use of a chain of custody form that documents the collection, transport, receipt, testing, and destruction of samples.

DOH DRAFT RULES

2. The chain of custody form shall include the sample location, the number and types of containers, the mode of collection, the authorized individual who collected the sample, the date and time of collection, and requested analyses.

Source: __

General Authority: SDCL 34-20G-72(5)(k)

Law Implemented: SDCL 34-20G-11

44:90:06:04. Reporting of test results.

1. The results of any analytical test of cannabis or cannabis products shall be provided to the cannabis cultivation facility or cannabis cultivation facility in the form of a certificate of analysis.
2. The cannabis testing facility shall update the inventory tracking system to reflect whether the analytical test has revealed the presence of any analyte that renders the cannabis or cannabis products non usable.

Source: __

General Authority: SDCL 34-20G-72(5)(d), 34-20G-72(5)(e), 34-20G-72(5)(h), and 34-20G-72(5)(k)

Law Implemented: SDCL 34-20G-9, SDCL 34-20G-10, and SDCL 34-20G-11

44:90:06:05. Analytical testing result verification.

DOH DRAFT RULES

1. Prior to July 1, 2024, all medical Cannabis or Cannabis products tested by state-certified laboratories shall be subject to routine confirmation testing by the department or department designee.
   (A) Upon request, the laboratory shall submit residual material from samples with complete testing results to the department or department designee.
   (B) The department or department designee will perform testing using an acceptable method to verify initial results.
   (C) Results of confirmation testing will be made available to the originating laboratory, and
      (1) If initial testing results are found to be conforming, no additional action will be taken;
      (2) If discordant results are encountered, the sample will be subjected to a third and final round of testing; and
      (3) If a third round of testing reveals discordant results, the cannabis testing facility shall stop all testing of cannabis and cannabis products pending completion of a corrective action plan approved by the department.
2. On or after July 1, 2024, the department shall not require routine confirmation testing for analytical tests within the scope of certification for an ISO/IEC 17025 certified cannabis testing facility, provided the cannabis testing facility:
   (A) Participates in a proficiency testing program as defined by the ISO17025 accrediting body;
   (B) Performs proficiency testing at an interval defined by the accrediting body; and
   (C) Achieves a passing score on each proficiency test, or in the event of a non-passing score, completes remediation as defined by the accrediting body.

Source: __

DOH DRAFT RULES

General Authority: SDCL 34-20G-72(5)(k)

Law Implemented: SDCL 34-20G-11 and 34-20G-69

CHAPTER 44:90:07

CANNABIS PRODUCT MANUFACTURING FACILITIES

Section

44:90:07:01	Manufacturing practices.
44:90:07:02	Prohibited manufacturing activities.
44:90:07:03	Extraction – Approved operating procedures.
44:90:07:04	Generally safe extraction methods.
44:90:07:05	Potentially hazardous extraction methods.
44:90:07:06	Extraction using inherently hazardous substances.
44:90:07:07	Edible cannabis products.

44:90:07:01. Manufacturing practices.

1. A cannabis product manufacturing facility must follow standard operating procedures to ensure workplace, environmental, and product safety, including:
   (A) Ensuring that all equipment and surfaces that come into contact with cannabis or other ingredients are food grade and nonreactive;
   (B) Maintaining all counters and surface areas in a manner that reduces the potential for development of microbials, molds, mildew, fungi and other contaminants;
   (C) Providing adequate refrigeration for ingredients and products during manufacture, storage, or transport;

DOH DRAFT RULES

(D) Ensuring that all electrical equipment is listed by a nationally recognized testing laboratory or inspected annually by a professional engineer licensed in South Dakota; and

(E) Storing all chemicals in a safe manner.

2. As applicable, all agents of a cannabis product manufacturing facility must:

(A) Work in an environment with proper ventilation, controlling all sources of ignition where a flammable atmosphere is or may be present;

(B) Use proper eye protection, respiratory protection and gloves;

(C) Use only water that is potable and ice that is made from potable water; and

(D) Undergo safety training on fire prevention and safe operation of equipment used for manufacturing.

3. Any cannabis product shall be considered non usable if it contains detectable levels of any of the following contaminants:

(A) Residual pesticides, unless approved by the department;

(B) Residual solvents other than ethanol, glycerin, propylene glycol, or cooking fats;

(C) Mold, yeast, or mycotoxins;

(D) Coliform bacteria, enterobacteriaceae, e. coli, or salmonella; or

(E) Cadmium, lead, arsenic, or mercury.

Source: __

General Authority: SDCL 34-20G-72(5)(d), 34-20G-72(5)(e) and 34-20G-72(5)(h)

Law Implemented: SDCL 34-20G-10

44:90:07:02. Prohibited manufacturing activities.

DOH DRAFT RULES

A cannabis product manufacturing facility may not:

1. Manufacture a product in the distinct shape of human, animal, creature, vehicle, fruit, cartoon character, toy, emoji, or other artwork likely or intended to appeal to anyone under 21 years of age;
2. Manufacture a cannabis product by adding or infusing cannabis into a commercially available non-cannabis end product;
3. Manufacture any edible cannabis product that has more than 10 milligrams of THC per serving;
4. Package in a marketing layer an edible cannabis product with more than 100 milligrams of total THC;
5. Manufacture a product using cannabis, concentrate, or extract that has not passed any test declared mandatory by the department;
6. Manufacture cannabis products intended for non-human consumption;
7. Manufacture products that do not contain cannabis on the same premises as cannabis products; or
8. Extract cannabis using pressurized canned flammable fuel, including butane or propane in containers intended for camp stoves, handheld torch devices, refillable cigarette lighters, or similar consumer products.

Source: __

General Authority: SDCL 34-20G-72(5)(g)

Law Implemented: SDCL 34-20G-10

44:90:07:03. Extraction – Approved operating procedures.

DOH DRAFT RULES

1. A cannabis product manufacturing facility must conform with the standard operating procedures for extraction methods described in its operating procedures and shall not extract cannabis using any other methods without prior written approval by the department.
2. A cannabis product manufacturing facility performing extraction may be subject to inspection by the state fire marshal, local fire department, building inspector or code enforcement officer to confirm that no health or safety concerns are present, and that the facility complies with all applicable safety standards contained in local ordinance, SDCL chapter 11-10, ARSD article 61:15, and ARSD chapter 20:44:22.

Source: __

General Authority: SDCL 34-20G-72(5)(g)

Law Implemented: SDCL 34-20G-10

44:90:07:04. Generally safe extraction methods.

The following methods of extraction are permissible if listed in the establishment's operating procedures on file with the department:

1. Mechanical extraction using:
   (A) Potable water and ice made from potable water;
   (B) Dry screening or sieving;
   (C) Cryogenic or subzero processing not involving a solvent; and
   (D) Pressure and temperature.
2. Infusion of cannabis in food grade fats or synthetic food additives:
   (A) Propylene glycol;
   (B) Glycerin; and
   (C) Butter, olive oil, or other typical cooking fats.

DOH DRAFT RULES

Source: __

General Authority: SDCL 34-20G-72(5)(g)

Law Implemented: SDCL 34-20G-10

44:90:07:05. Potentially hazardous extraction methods.

The department will permit extraction using the following substances, if 99 percent or greater in purity and if the department deems storage, preparation, electrical, gas monitoring, fire suppression, and exhaust systems methods to be adequate:

1. Carbon dioxide;
2. Another liquid chemical, compressed gas, or commercial product that has a flashpoint above 100 degrees Fahrenheit; or
3. Ethanol, including solutions of ethanol and water;

Source: __

General Authority: SDCL 34-20G-72(5)(g)

Law Implemented: SDCL 34-20G-10

44:90:07:06. Extraction using inherently hazardous substances.

1. Extraction using an inherently hazardous substance requires prior physical inspection and written approval by a professional engineer licensed in South Dakota that the establishment's storage, preparation, electrical, gas monitoring, fire suppression, and exhaust systems are adequate.
2. Any extraction method using inherently hazardous substances must be listed in the operating procedures on file with the department and use an agent of 99 percent or greater purity.

DOH DRAFT RULES

3. The resulting extract shall not exceed residual limits for the solvent established by the department as part of testing requirements.
4. The following solvents may be used in approved inherently hazardous extraction:
   (A) Butane;
   (B) Propane;
   (C) Acetone;
   (D) Heptane; or
   (E) Pentane.
5. Any other inherently hazardous substance shall be approved only upon written application to the Department explaining the safety and efficacy of the selected method.
6. All flammable gas must be odorized in compliance with state and federal regulations.

Source: __

General Authority: SDCL 34-20G-72(5)(g)

Law Implemented: SDCL 34-20G-10

44:90:07:07. Edible cannabis products.

A cannabis product manufacturing facility that has declared edible cannabis products as part of their operating plan of record must:

1. Obtain a South Dakota food service establishment license, pursuant to SDCL chapter 34-18, covering ongoing activities at the location identified in the operating plan;
2. Employ a Certified Food Service Manager meeting department specifications;
3. Comply with all applicable standards of ARSD 44:02:07, and the city or county in which the establishment is located.

DOH DRAFT RULES

Source: __

General Authority: SDCL 34-20G-72(5)(g)

Law Implemented: SDCL 34-20G-10

CHAPTER 44:90:08

CANNABIS DISPENSARIES

Section

44:90:08:01 Preventing unauthorized access – Age verification.

44:90:08:02 Preventing unauthorized sales – Training requirements.

44:90:08:01. Preventing unauthorized access – Age verification.

1. No dispensary shall allow entry into areas containing cannabis without first identifying an individual as a cardholder or other person authorized pursuant to ARSD 44:90:04:14.
2. No dispensary shall allow entry to a patient who is under 21 years of age.
3. Acceptable methods of controlling access include:
   (A) Verification at an external cashier window or ticket window, followed by unlocking an exterior door to admit the individual into the building;
   (B) Verification at a cashier window or ticket window located in an entryway with a locked interior door that prevents access to any area containing cannabis, followed by unlocking the interior door; and

DOH DRAFT RULES

(C) Verification by an agent outside a locked exterior or interior door, followed by unlocking the door.

4. Verification shall not take place in any area in which a person may access cannabis without passing through a lockable door.

5. Any website or mobile application developed or hosted by an establishment shall:

   (A) Include verification that the visitor is 21 years of age or older;

   (B) Require the cardholder's or nonresident cardholder's registry identification number for verification of any online purchases; and

   (C) Limit online sales to cardholders and nonresident cardholders who previously have made a purchase of cannabis or cannabis products at the dispensary.

Source: __

General Authority: SDCL 34-20G-72(5)(c)

Law Implemented: SDCL 34-20G-64

44:90:08:02. Preventing unauthorized sales – Training requirements.

Before interacting with any cardholder, all employees of a dispensary shall be trained to:

1. Determine the authenticity of registry identification cards, including temporary registry identification cards and nonresident registration credentials;
2. Ensure that the person presenting a temporary or department-issued registry identification card or nonresident registration credential is the authorized cardholder;

DOH DRAFT RULES

3. Use the verification system, including all options for accessing the system by phone, point-of-sale software, or mobile application;
4. Track the amount of cannabis dispensed for a patient's use, including consolidating the amounts in sales to the patient and the patient's caregiver; and
5. Verify that the dispensary has been designated to make sales to the patient or the patient's designated caregiver.

Source: __

General Authority: SDCL 34-20G-72(5)(g)

Law Implemented: SDCL 34-20G-70 and 34-20G-71

CHAPTER 44:90:09

SAMPLING AND TESTING

44:90:09:01 Mandatory testing prior to transfer.

44:90:09:02 Creation of batches – Collection of samples.

44:90:09:03 Packaging of samples for testing.

44:90:09:01. Mandatory testing prior to transfer.

1. No cannabis or cannabis products shall be transferred by a cannabis cultivation facility or cannabis product manufacturing facility to a cannabis product manufacturing facility or cannabis dispensary unless:
   (A) A cannabis testing facility has tested the cannabis or cannabis product and determined it to be in compliance with this article; and

DOH DRAFT RULES

(B) The cannabis or cannabis product is accompanied by a certificate of analysis issued by the cannabis testing facility.

2. Except samples for testing, any cannabis or cannabis products transferred from a cannabis cultivation facility or a cannabis product manufacturing facility without a certificate of analysis shall be considered non usable.
3. A cannabis product manufacturing facility or cannabis dispensary shall maintain the certificate of analysis for any cannabis or cannabis product for 180 days or until all of the cannabis or cannabis product has been transferred or disposed of, whichever is later.
4. The licensee submitting the cannabis or cannabis product for testing shall pay all fees associated with this testing.

Source: __

General Authority: SDCL 34-20G-72(5)(d) and 34-20G-72(5)(e)

Law Implemented: SDCL 34-20G-9, 34-20G-10, and 34-20G-11

44:90:09:02 Creation of batches -- Collection of samples.

1. A cannabis cultivation facility or cannabis product manufacturing facility must:

   (A) Divide cannabis or cannabis products into batches as directed by a registered cannabis testing facility; and

   (B) Assign a unique batch identifier to the cannabis or cannabis product.

2. When cannabis is harvested or trimmed:

DOH DRAFT RULES

(A) Cannabis flower shall be assigned to a batch containing a single strain from single harvest date; and

(B) Cannabis trim may be assigned to a batch containing multiple strains and from multiple trimming dates.

3. A cannabis cultivation facility or cannabis product manufacturing facility must submit for laboratory testing at minimum one sample from of each batch of cannabis or cannabis product or as directed by the cannabis testing facility based on batch size.
4. All collections of samples for testing to be performed by a cannabis testing facility shall be performed by an agent of either the testing facility or the establishment submitting the sample.
5. The collection of samples shall comply in all manner with the testing facility's standard operating procedures.

Source: __

General Authority: SDCL 34-20G-72(5)(k)

Law Implemented: SDCL 34-20G-11

44:90:10:03. Packaging of samples for testing.

All samples of cannabis, cannabis extracts, or cannabis products shall be transferred to a testing facility in sealed, child-resistant, and tamper-evident containers that are supplied by a testing facility or that meet criteria specified by a testing facility.

Source: __

General Authority: SDCL 34-20G-72(5)(k)

DOH DRAFT RULES

Law Implemented: SDCL 34-20G-11

44:90:10:04. Receipt of results.

1. Upon receipt of a certificate of analysis indicating that cannabis or cannabis products comply with SDCL chapter 34-20G and this article, the cannabis cultivation facility or cannabis product manufacturing facility may transfer the cannabis or cannabis products to another establishment, subject to this article.
2. Upon receipt of a certificate of analysis indicating that cannabis or cannabis products are non usable, the cannabis or cannabis shall not be transferred and may be subject to destruction according to this article.

DOH DRAFT RULES

CHAPTER 44:90:10

PACKAGING, LABELING, AND ADVERTISING

Section

44:90:10:01	Packaging for transfer or sale - General requirements.
44:90:10:02	Packaging for retail sale – General requirements.
44:90:10:03	Packaging of cannabis flower or trim or inhaled cannabis products for retail sale.
44:90:10:04	Packaging of edible cannabis products for retail sale - Tinctures, oils, and beverages excluded.
44:90:10:05	Packaging of cannabis tinctures and oils for retail sale.
44:90:10:06	Packaging of cannabis beverages for retail sale.
44:90:10:07	Packaging of topical cannabis products for retail sale.

44:90:10:08 Labeling required.

44:90:10:09 Format of labeling – Font size – Multiple labels.

44:90:10:10 Labeling claims – Results of testing.

44:90:10:11 Expected effects – Time to take effect – Duration of effect.

44:90:10:12 Ingredients – Allergen warnings.

44:90:10:13 Contents – Net weight or volume -- Nutritional information.

44:90:10:14 Required warnings – Indication that edible product contains cannabis – Side effects – Legal status of cannabis.

44:90:10:15 Identifying information – Establishment identification number – Batch -- Dates.

44:90:10:16 Labeling prohibitions.

44:90:10:17 Prohibited forms of advertising.

44:90:10:18 Target audience – Establishments and adult cardholders only – Prohibition on advertising to practitioners.

44:90:10:19 Prohibited content – Advertisements.

44:90:10:20 Required information.

44:90:10:21 Nonconforming advertising.

44:90:10:01. Packaging for transfer or sale -- General requirements.

1. All cannabis or cannabis products must be packaged for transfer or sale in containers that:

   (A) Are fully enclosable;

   (B) Are resealable;

   (C) Protect the packaged item from contamination; and

   (D) Do not impart any toxic or deleterious substance to the packaged item.

2. A cultivation facility shall package all flower, trim, or pre-rolled cigarettes for retail sale before transfer to a dispensary.

DOH DRAFT RULES

3. A cannabis product manufacturing facility shall package all cannabis products for retail sale before transfer to a dispensary.

Source: __

General Authority: SDCL 34-20G-72(5)(j)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

44:90:10:02. Packaging for retail sale – General requirements.

1. A dispensary must transfer any cannabis, cannabis concentrate, or cannabis products to the patient or caregiver in packaging that is:
   (A) Child-resistant in compliance with compliant with 16 CFR part 1700 (2020);
   (B) Tamper-evident, using a sealing method that provides clear, lasting evidence that the packaged has previously been opened;
   (C) Resealable, except for single-serving cannabis products; and
   (D) Opaque.
2. Unless otherwise specified by this article, each packaging requirement may be met either by the container provided by the cultivation facility or cannabis product manufacturing facility or by exit packaging supplied by the dispensary at the time of sale.

Source: __

General Authority: SDCL 34-20G-72(5)(j)

Law Implemented: SDCL 34-20G-8, 34-20G-9, and 34-20G-10

DOH DRAFT RULES

44:90:10:03. Packaging of cannabis flower or trim or inhaled cannabis products for retail sale.

Cannabis flower or trim or an inhaled cannabis product shall be transferred by a dispensary only in a container that is fully enclosed on all sides, as follows:

1. If the container is soft sided, it must be four mil or greater in thickness; or
2. If container has rigid sides, it must have a lid or enclosure that can be placed tightly and securely on the container.

Source: __

General Authority: SDCL 34-20G-72(5)(j)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

44:90:10:04. Packaging of edible cannabis products for retail sale -- Tinctures, oils, and beverages excluded.

1. Single-serving edible cannabis products:
   (A) Shall be placed into a child-resistant container that may or may not be resealable; and
   (B) May be bundled into a larger marketing layer so long as the total amount of active THC per marketing layer does not exceed 100 milligrams.
2. Multiple-serving edible cannabis products:
   (A) Shall either be placed into either a resealable container or with individual servings heat-sealed into packaging made of plastic four mil or greater in thickness with no easy-open tab, dimple, corner or flap;
   (B) Shall contain 100 milligrams or less of total THC per multiple-serving container; and

DOH DRAFT RULES

(C) Shall clearly indicate the size of a serving if the edible product is not in a form that indicates a serving.

Source: __

General Authority: SDCL 34-20G-72(5)(j)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

44:90:10:05. Packaging of cannabis tinctures and oils for retail sale.

1. A cannabis tincture or oil shall be packaged in a glass or plastic vial, either:
   (A) With a resealable child-resistant cap; or
   (B) With a resealable cap and enclosed in a child-resistant soft-sided container made of plastic four mil or greater in thickness and heat sealed.
2. The packaging shall include a measuring device such as a measuring cap or dropper. Hash marks on the bottle or package do not qualify as a measuring device.

Source: __

General Authority: SDCL 34-20G-72(5)(j)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

44:90:10:06. Packaging of cannabis beverages for retail sale.

1. Single-serving cannabis beverages that do not contain more than 10 milligrams of THC shall be packaged in:
   (A) A child-resistant container; or
   (B) A metal can with a stay tab mechanism opening; or
   (C) A glass bottle with a cork or metal crown style bottle cap.

DOH DRAFT RULES

2. Multiple-serving cannabis beverages that contain more than 10 milligrams of THC but no more than 100 milligrams of THC shall:
   (A) Be packaged in a child-resistant container that has a resealing cap or closure; and
   (B) Include a measuring device such as a measuring cap or dropper; hash marks on the bottle or package do not qualify as a measuring device.
3. Cannabis beverages packaged according to this section may be bundled into a larger marketing layer so long as the total amount of THC per marketing layer does not exceed 100 milligrams.

Source: __

General Authority: SDCL 34-20G-72(5)(j)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

44:90:10:07. Packaging of topical cannabis products for retail sale.

1. Salves, creams, lotions and balms shall be packaged in a child-resistant container that has a resealing cap or closure compliant with 16 CFR part 1700 (2020).
2. Transdermal patches shall be packaged in a plastic four mil or greater in thickness to prevent unintended access to and ingestion by children or pets and be heat sealed with no easy-open tab, dimple, corner or flap, as to make it difficult for a child to open.

Source: __

General Authority: SDCL 34-20G-72(5)(j)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

44:90:10:08. Labeling required.

DOH DRAFT RULES

1. All cannabis, cannabis extract, and cannabis products shall be labeled in accordance with this chapter before sale or transfer to the patient or caregiver.
   (A) Prior to transferring cannabis to a dispensary, a cultivation facility must label the marketing layer of each container.
   (B) Prior to transferring cannabis products to a dispensary, a cannabis product manufacturing facility must label each the marketing layer of each container.
2. Unless otherwise specified, all required information may be printed directly on, or printed on a sticker attached to the marketing layer of the cannabis, cannabis extract, or cannabis product.

Source: __

General Authority: SDCL 34-20G-72(7)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

44:90:10:09. Format of labeling – Font size – Multiple labels.

All required information shall be printed clearly in English in type no smaller than 6-point font (1/12 inch). An establishment may affix an extendable, accordion-style, label, layered label, or multiple labels to the marketing layer, provided none of the required information is obstructed and the label can be easily identified by a patient or caregiver as containing important information.

Source: __

General Authority: SDCL 34-20G-72(7)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

DOH DRAFT RULES

44:90:10:10. Labeling claims -- Results of testing.

1. The results of any testing mandated by the department shall be included on the label of any cannabis or cannabis product.
2. No label shall contain claims regarding cannabinoid potency or the absence of microbials, metals, solvents, or pesticides except to list the results of analytical tests performed by a registered cannabis testing facility.

Source: __

General Authority: SDCL 34-20G-72(7)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

44:90:10:11. Expected effects – Time to take effect – Duration of effect.

1. The label of any cannabis or cannabis product shall indicate:
   (A) The length of time, in hours or minutes, that it may take the patient to feel effects; and
   (B) The length of time the patient should expect the effects to last.
2. The estimated time to take effect and duration of effect shall be based on the best estimate of the establishment printing the label.
3. All edible products, except ethanol-based tinctures, shall additionally contain the following warning: "Effects of this product may not be felt for up to 4 hours."

Source: __

General Authority: SDCL 34-20G-72(7)(a)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

44:90:10:12. Ingredients – Allergen warnings.

DOH DRAFT RULES

1. The label of any cannabis or cannabis product shall identify any pesticides used in cultivation.
2. The label of any cannabis product shall list all ingredients and, if applicable, gases, solvents, or other chemicals used in extraction.
3. The label of any edible cannabis product shall identify any major allergens contained in the product in accordance with 21 USC section 343 (2021), including milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans.

Source: __

General Authority: SDCL 34-20G-72(7)(c)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

44:90:10:13. Contents – Net weight or volume -- Nutritional information.

1. The label's statement of net contents shall identify the net weight or volume of the cannabis, cannabis extract, or cannabis product, expressed:
   (A) If a solid, in both ounces and grams/milligrams; or
   (B) If a liquid or colloid, in both fluid ounces and milliliters.
2. The label of any cannabis product shall state the equivalent cannabis weight, calculated according to the equivalent cannabis weight table included in section 44:90:02:10 of this article.
3. The label of any edible cannabis product shall identify the size, expressed in ounces and grams/milligrams, fluid ounces or millimeters, or number of pieces, of a serving providing 10 mg of THC and the number of servings per marketing layer;

DOH DRAFT RULES

4. The label of vaporizing cartridges, pens, and topical cannabis products shall be expressed in the weight of concentrate used to manufacture the product within the marketing layer in milligrams or grams and ounces.
5. Any edible cannabis product shall be labeled with a nutritional fact panel in accordance with 21 CFR part 101 (2018).

Source: __

General Authority: SDCL 34-20G-72(7)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

44:90:10:14. Required warnings -- Indication that edible product contains cannabis – Side effects – Legal status of cannabis.

1. The department shall design a standard symbol that indicates an item contains cannabis or cannabis extract, which shall be used by all registered establishments.
2. This standard symbol shall appear on the front or most predominantly displayed area of the marketing layer of an edible cannabis product, no smaller than 1/2 inch by 1/2 inch.
3. All cannabis and cannabis products shall carry the following warning statement in no smaller than 6-point font: "For medical use by qualifying patients only. There may be health risks associated with the use of this product. There may be additional health risks associated with the use of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant. Do not drive a motor vehicle or operate heavy machinery while using this product."

Source: __

General Authority: SDCL 34-20G-72(7)(d)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

DOH DRAFT RULES

44:90:10:15. Identifying information – Establishment identification number – Batch -- Dates.

The container or exit packaging for any cannabis or cannabis product sold by a dispensary shall identify:

1. The registration number of any cultivation facility, cannabis product manufacturing facility, or dispensary involved in the cultivation, processing, or sale of the item;
2. Batch numbers;
3. Cultivation date of cannabis flower or trim; and
4. Production date of cannabis products

Source: __

General Authority: SDCL 34-20G-72(7)(d)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

44:90:10:16. Labeling prohibitions.

No label shall:

1. Include representations as to cannabinoid content or to the absence of pesticides, mold, or other contaminants, other than to provide the results of analysis performed by a testing laboratory certified in accordance with this article;
2. Make claims regarding health or physical benefits to the consumer;
3. Include any false or misleading statements;
4. Obscure identifying information or warning statements;
5. Use any trademark without authorization;

DOH DRAFT RULES

6. Depict a human, animal, creature, vehicle, fruit, cartoon character, toy, emoji, or other artwork likely or intended to appeal to anyone under 21 years of age;
7. Include the word "candy" or "candies"; or
8. Refer to any item typically marketed to persons under 21 years of age.

Source: __

General Authority: SDCL 34-20G-72(7)(d)

Law Implemented: SDCL 34-20G-9 and 34-20G-10

44:90:10:17. Prohibited forms of advertising.

No establishment shall advertise:

1. On a sign or billboard, except that a dispensary may advertise on signs on its own premises;
2. By distributing handbills in public areas or on publicly owned property;
3. Through direct mail, phone, text, or email without verifying the recipient is a cardholder or medical cannabis establishment and offering a permanent opt-out feature;
4. On television or radio;
5. Through a practitioner or health care facility, including placement of advertising material onsite or targeting their patients through direct mail, phone, text, or email.

Source: __

General Authority: SDCL 34-20G-72(5)(i)

Law Implemented: SDCL 34-20G-33 and 34-20G-78

44:90:10:18. Target audience – Establishments and adult cardholders only – Prohibition on advertising to practitioners.

DOH DRAFT RULES

1. Advertisements shall be targeted as directly as possible to:

   (A) Other establishments;

   (B) Cardholders who are 21 years of age or older; and

   (C) Readers of medical publications.

2. Advertisements may not target:

   (A) Non-cardholders, including:

      (1) Suggesting a medical evaluation; or

      (2) Interacting with the public at events sponsored by the establishment;

   (B) Anyone under the age of 21, including:

      (1) Depicting anyone under 21 years of age; or

      (2) Using cartoons, toys, or other products or images commonly associated with or marketed to individuals under 21 years of age; or

   (C) Practitioners or health care facilities, other than advertising in medical publications.

3. Any advertising on websites, social media, or mobile applications shall include:

   (A) A verification that the recipient is a cardholder 21 years of age or older; and

   (B) A permanent opt-out feature.

Source: __

General Authority: SDCL 34-20G-72(5)(i)

Law Implemented: SDCL 34-20G-33, 34-20G-74 and 34-20G-78

44:90:10:19. Prohibited content – Advertisements.

No advertisement for a medical cannabis establishment shall:

1. Make deceptive, false or misleading statements;

DOH DRAFT RULES

2. Make claims related to potency (beyond listing of cannabinoid content verified by a testing facility);
3. Depict consumption of cannabis or cannabis products;
4. Depict pregnancy, breastfeeding, or operating a motorized vehicle, boat or machinery;
5. Depict or refer to candy or a specific type of candy;
6. Use a trademark associated with a non-cannabis product, including parody or other use that has similarity to the original;
7. Encourage the transportation of cannabis across state lines or otherwise encourage illegal activity;
8. Assert that cannabis is safe because it is regulated by the department, tested by a testing facility, or otherwise endorsed by any government agency;
9. Make claims that cannabis has curative or therapeutic effects;
10. Claim any health or physical benefits; or
11. Encourage excessive or rapid consumption.

Source: __

General Authority: SDCL 34-20G-72(5)(i)

Law Implemented: SDCL 34-20G-7

44:90:10:20. Required information.

Any advertisement shall contain the following information:

1. A statement "For medical use by qualifying patients only"; and
2. The medical cannabis establishment identification number.

Source: __

DOH DRAFT RULES

General Authority: SDCL 34-20G-72(5)(i)

Law Implemented: SDCL 34-20G-7

44:90:10:21. Nonconforming advertising.

1. Any nonconforming advertising shall be considered a violation of this article and SDCL chapter 34-20G.
2. Upon notification by the department, the establishment shall cease the nonconforming advertisements and remove any nonconforming advertising from websites, social media, mobile applications, or signs.
3. Failure to cease or remove the advertising within 48 hours shall be considered a serious and knowing violation of this article and SDCL chapter 34-20G.

Source: __

General Authority: SDCL 34-20G-72(5)(i)

Law Implemented: SDCL 34-20G-80

CHAPTER 44:90:11

RECORDKEEPING

Section

44:90:11:01 Inventory tracking system – Required use.

44:90:11:02 Retention of records – Electronic and paper – Amended records.

44:90:11:03 Daily inventory record.

44:90:11:04 Daily transfer record.

44:90:11:05 Daily testing sample record.

DOH DRAFT RULES

44:90:11:06 Cultivation facility inventory records – Additional requirements.

44:90:11:07 Cannabis product manufacturing facility inventory records – Additional requirements.

44:90:11:08 Testing facility inventory records – Additional requirements.

44:90:11:09 Dispensary inventory records – Additional requirements.

44:90:11:10 Daily transaction record.

44:90:11:11 Department access to and use of establishment records.

44:90:11:01. Inventory tracking system – Required use.

Establishments are required to use an electronic inventory tracking system prescribed by the department to create all required inventory records, transfer records, testing sample records, and transaction records.

Source: __

General Authority: SDCL 34-20G-72(5)(b)

Law Implemented: SDCL 34-20G-63

44:90:11:02. Retention of records -- Electronic and paper – Amended records.

1. A cannabis establishment must maintain, for a minimum of 18 months, records to enable the department to identify and prevent diversion of cannabis and to protect patients from unsafe cannabis and cannabis products, including:
   (A) All point of sale records, whether in electronic or paper form;
   (B) Transport manifests; and
   (C) Daily inventory records, transfer records, testing sample records, and transaction records.
2. No inventory record, transfer record, testing sample record, or transaction record shall be altered after the date on which it was created.

DOH DRAFT RULES

3. If necessary, an amended inventory record, transfer record, testing sample record, or transaction record may be created, but the original record shall be subject to record retention requirements.

Source: __

General Authority: SDCL 34-20G-72(5)(b)

Law Implemented: SDCL 34-20G-63

44:90:11:03. Daily inventory record.

1. A cannabis establishment must maintain and update by midnight each day of operation, an electronic record of the establishment's inventory of cannabis, including seeds, seedlings, plants, extracts, products, and waste.
2. The inventory record shall use the following units of measure:
   (A) Seeds, seedlings, and plants shall be quantified in whole numbers;
   (B) Quantities of cannabis flower, trim, extracts, or pre-rolled cannabis cigarettes shall be expressed in grams and ounces;
   (C) Quantities of edible cannabis products shall be expressed in whole numbers of servings, each providing 10 mg of THC;
   (D) Quantities of vaporizing cartridges, pens, and transdermal patches shall be expressed in the number of marketing layers and the net weight of concentrate per marketing layer in milligrams.
   (E) Quantities of topical cannabis products other than transdermal patches shall be expressed in the number of marketing layers and the net volume of the topical product in fluid ounces.

DOH DRAFT RULES

3. The inventory record shall reflect:

   (A) The destruction of cannabis or disposal of cannabis waste;

   (B) Theft or other loss; and

   (C) Data from the transfer record.

4. The inventory record shall be maintained securely and shall not identify any cardholder other than by the cardholder's identification number.

Source: __

General Authority: SDCL 34-20G-72(5)(b)

Law Implemented: SDCL 34-20G-63

44:90:11:04. Daily transfer record.

1. A cannabis establishment must maintain and update by midnight, an electronic record of all cannabis, including any seeds, plants, extracts, or products, obtained from a cardholder or another establishment, and all cannabis transferred to another establishment.
2. The transfer record shall use the same units of measure as the inventory record.
3. The transfer record shall reflect all transport manifests.
4. The transfer record shall be maintained securely and shall not identify any cardholder except by the cardholder's identification number.

Source: __

General Authority: SDCL 34-20G-72(5)(b)

Law Implemented: SDCL 34-20G-63

44:90:11:05. Daily testing sample record.

DOH DRAFT RULES

1. A cannabis establishment must maintain and update by midnight, an electronic testing sample record, including:
   (A) The batch identifier and quantity of each batch from which samples were drawn;
   (B) The sample identifier of each sample created, its quantity, and the batch identifier associated with the sample;
   (C) The tests to be performed; and
   (D) Test results, including a note of whether the testing facility has indicated the batch is safe or unsafe for transfer to another establishment.
2. The quantity of each batch and each sample shall be expressed in the same units as the inventory record.

Source: __

General Authority: SDCL 34-20G-72(5)(b)

Law Implemented: SDCL 34-20G-63

44:90:11:06. Cultivation facility inventory records – Additional requirements.

1. The inventory record of a cultivation facility shall include a unique identifier for each seedling or plant greater than 12 inches in height, which shall also be printed on a tag or label affixed to the growing container or a tag around the plant's stalk.
2. The inventory record shall be updated each time:
   (A) A seedling exceeds its size limit and is considered a plant;
   (B) A plant flowers for the first time;
   (C) A plant is trimmed or harvested;
   (D) A testing batch is created; or

DOH DRAFT RULES

(E) Cannabis is packaged for retail sale.

3. The record for a testing batch must indicate the unique identifier for each plant used to produce the batch.
4. The record for cannabis packaged and labeled for transfer to a dispensary shall include the number of marketing layers and the quantity of cannabis in each marketing layer, as expressed according to the relevant labeling requirement.

Source: __

General Authority: SDCL 34-20G-72(5)(b)

Law Implemented: SDCL 34-20G-63 and 34-20G-88

44:90:11:07. Cannabis product manufacturing facility inventory records – Additional requirements.

1. The inventory record of a cannabis product manufacturing facility shall include the batch identification number of each testing batch of cannabis obtained from a cultivation facility.
2. The inventory record shall be updated each time:
   (A) A quantity of extract or concentrated cannabis is made from cannabis flower or trim;
   (B) A quantity of cannabis product is made from concentrated cannabis, cannabis extract, flower, or trim; or
   (C) A quantity of cannabis product is packaged for retail sale.
3. Any extract must be assigned to a testing batch, which shall:
   (A) Consist only of extract produced on a single day using the same extraction method; and
   (B) Be entered into the inventory record with the identifier of any testing batch of cannabis from which it was produced.

DOH DRAFT RULES

4. Any cannabis product must be assigned to a testing batch, which shall:
   (A) Consist only of a single type of product produced on a single day; and
   (B) Be entered into the inventory record with the identifier or any testing batch of cannabis or cannabis extract from which it was produced.
5. The record for cannabis extracts or products packaged and labeled for transfer to a dispensary shall include the testing batch identifier, the number of marketing layers, and the quantity of cannabis in each marketing layer, as expressed according to the relevant labeling requirement.

Source: __

General Authority: SDCL 34-20G-72(5)(b)

Law Implemented: SDCL 34-20G-63 and 34-20G-88

44:90:11:08. Testing facility inventory records – Additional requirements.

1. A testing facility shall maintain and update by midnight each day of operation, an inventory record of:
   (A) All samples in its possession, with unique identifiers and quantities expressed in units specified in its operating procedures; and
   (B) All other cannabis, cannabis extracts, and cannabis products acquired for training or reference purposes;
2. The inventory record shall reflect:
   (A) The quantity of each sample rendered unusable by testing;
   (B) The quantity of each sample returned to the establishment;
   (C) The quantity of each sample destroyed or disposed of; and

DOH DRAFT RULES

(D) The quantity of any sample lost, stolen, or otherwise unaccounted for.

Source: __

General Authority: SDCL 34-20G-72(5)(b)

Law Implemented: SDCL 34-20G-63 and 34-20G-88

44:90:11:09. Dispensary inventory records – Additional requirements.

1. The inventory record of a dispensary shall include all cannabis, cannabis extracts, and cannabis products, including the type of product, the testing batch identifier, the number of marketing layers, and the quantity of cannabis in each marketing layer, as expressed according to the relevant labeling requirement.
2. The inventory record shall be updated each day of operation to reflect:
   (A) Any cannabis, cannabis extracts, or cannabis products received from another establishment;
   (B) Sales to qualifying cardholders, which shall include the cardholder's identification number;
   (C) Returns of merchandise from cardholders, whether to be resold, returned to another establishment, or destroyed;
   (D) Transfers to another establishment, including returns; and
   (E) Destruction of cannabis.

Source: __

General Authority: SDCL 34-20G-72(5)(b)

Law Implemented: SDCL 34-20G-63 and 34-20G-88

DOH DRAFT RULES

44:90:11:10. Daily transaction record.

1. A dispensary shall maintain and shall update by midnight each day of operation, a transaction record, which shall include:
   (A) The type of product, the testing batch identifier, the number of marketing layers, and the quantity of cannabis in each marketing layer, as expressed according to the relevant labeling requirement, for each sale or return; and
   (B) The cardholder identification number associated with each quantity.
2. The transaction record shall contain no other identifying information relating to a cardholder.

Source: __

General Authority: SDCL 34-20G-72(5)(b)

Law Implemented: SDCL 34-20G-63 and 34-20G-71

44:90:11:11. Department access to and use of establishment records.

1. The department's agents:
   (A) Shall have access to all records, including transport manifests during an inspection of an establishment or vehicle, or in response to a written or telephone inquiry.
   (B) May compare inventory onsite or in delivery vehicles to the establishment's inventory records.
   (C) May compare transport manifests or observed deliveries to the establishment's transfer records.
2. Upon the discovery of any inconsistencies in the establishment's record-keeping, the department shall:

DOH DRAFT RULES

(A) Make a determination of whether the inconsistences are knowing or negligent;

(B) Inform the establishment in writing of its findings;

(C) If applicable, initiate suspension or revocation proceedings; and

(D) If applicable, refer possible criminal violations to state and local law enforcement.

Source: __

General Authority: SDCL 34-20G-72(5)(b)

Law Implemented: SDCL 34-20G-63 and SDCL 34-20G-88

DOH DRAFT RULES

CHAPTER 44:90:12

ENFORCEMENT

Section

44:90:12:01	Department inspection of establishments – Corrective action plan.
44:90:12:02	Suspension or revocation of registration certificates for serious violations.
44:90:12:03	Suspension or revocation of a registration certificate for multiple violations.
44:90:12:04	Voluntary surrender of registration certificate.
44:90:12:05	Revocation of registry identification card for unauthorized sale.
44:90:12:06	Revocation of registry identification card for serious or multiple violations.

44:90:12:01. Department inspection of establishments – Corrective action plan.

1. Agents of the department may conduct routine, unannounced inspections and inspections in response to complaints.

2. Agents of the department:

   (A) Must present identification before commencing an inspection of an establishment;

   (B) Shall have complete and unrestricted access to establishments during business hours or when establishment agents are present for the purposes of inspections, sample collection, testing, interviews, or other investigations;

   (C) May collect samples of cannabis and cannabis products and perform analytical tests on those samples or submit them to a cannabis testing facility for testing;

   (D) May inspect the contents of any vehicle used by an establishment to transport cannabis, cannabis extracts, or cannabis products, examine the manifest; and

   (E) Shall have access to inventory records and certificates of analysis maintained by the establishment, including collecting paper or electronic copies for further review.

3. The department shall provide an establishment the results of any analytical tests performed on samples taken from the establishment and shall inform the establishment whether the cannabis or cannabis products from which the samples were taken are non usable;

4. Upon the discovery of suspected violations of this article or SDCL chapter 34-20G, agents of the department may order the establishment to comply with a corrective action plan, which may include:

   (A) Modifying operating procedures to comply with this article and SDCL chapter 34-20G;

   (B) Halting transfer of cannabis or cannabis products that are mislabeled or otherwise pose a threat to public health; and

   (C) Destroying or remediating cannabis or cannabis products that pose a threat to public health.

Source: __

General Authority: SDCL 34-20G-72(6)

DOH DRAFT RULES

Law Implemented: SDCL 34-20G-69

44:90:12:02. Suspension or revocation of registration certificates for serious violations.

1. The department may, pursuant to SDCL chapter 1-26 and SDCL 34-20G-81, suspend for up to six months or revoke a registration certificate for any knowing violation of this article or SDCL chapter 34-20G that involves dishonesty, diversion, or threat to public health or safety, including knowingly:
   (A) Selling or otherwise transferring cannabis in exchange for anything of value to a person other than a cardholder, a nonresident cardholder, or to a medical cannabis establishment or its agent;
   (B) Making a false statement to a law enforcement official;
   (C) Sharing confidential information about a cardholder for monetary gain or to cause harm to the cardholder;
   (D) Submitting false records or documentation required by the department to certify a medical cannabis establishment;
   (E) Failing to meet obligations or conditions agreed to in the application for a registration certificate;
   (F) Dispensing, transferring, or selling cannabis while a registration certificate is suspended;
   (G) Obtaining cannabis seeds, cannabis seedlings, cannabis plants, cannabis, cannabis extract, or cannabis products in violation of this article or SDCL chapter 34-20G;
   (H) Failing to enter cannabis seedlings, cannabis plants, cannabis, cannabis extracts, or cannabis products into the establishment's inventory records;
   (I) Applying pesticides to cannabis plants without following all requirements of this article;

DOH DRAFT RULES

(J) Using solvents without authorization or in an unsafe manner;

(K) Misrepresenting the results of laboratory analysis

(L) Transferring non usable cannabis or cannabis products; or

(M) Committing any misdemeanor or felony offense in connection with the operation of a medical cannabis establishment.

2. Upon the discovery of violations that pose an ongoing threat to public health, safety, or welfare, the department may initiate emergency suspension proceedings pursuant to SDCL 1-26-29.

Source: __

General Authority: SDCL 34-20G-72(6)

Law Implemented: SDCL 34-20G-80 and 34-20G-81

44:90:12:03. Suspension or revocation of a registration certificate for multiple violations.

1. The department may, pursuant to SDCL chapter 1-26 and SDCL 34-20G-81, suspend for up to six months or revoke a registration certificate upon finding that the establishment has committed multiple violations of this article or SDCL chapter 34-20G, including:

(A) Serious violations of this article or SDCL chapter 34-20G;

(B) Negligent violations of this article or SDCL chapter 34-20G;

(C) Deviation from operating procedures in a manner that poses a threat to public safety or health, including the availability of cannabis, cannabis extract, or cannabis products to qualifying patients, including low-income qualifying patients;

(D) Sharing a cardholder's personal information;

DOH DRAFT RULES

(E) Minor or technical violations of this article that did not result in diversion of cannabis or harm to public health or safety;

(F) Violations of local ordinances governing the time, place, and manner of a medical cannabis establishment that may operate in the locality;

(G) Failure to allow agents of the department or any law enforcement agency access to an establishment during normal business hours; or

(H) Failure to provide a notice required by this article or SDCL chapter 34-20G.

(1) Upon the discovery of violations that pose an ongoing threat to public health, safety, or welfare, the department may initiate emergency suspension proceedings pursuant to SDCL 1-26-29.

Source: __

General Authority: SDCL 34-20G-72(6)

Law Implemented: SDCL 34-20G-80 and 34-20G-81

44:90:12:04. Voluntary surrender of registration certificate.

An establishment may offer to voluntarily surrender its registration certificate, cease operations, and may not renew or transfer the registration certificate. In such cases, the department has the discretion:

1. To reject voluntary surrender;
2. To accept the voluntary surrender without conditions; or
3. To negotiate conditions of a voluntary surrender, including the amount of time before which the establishment or any principal officer or board member may apply for a registration certificate.

DOH DRAFT RULES

Source: __

General Authority: SDCL 34-20G-72(6)

Law Implemented: SDCL 34-20G-80 and 34-20G-81

44:90:12:05. Revocation of registry identification card for unauthorized sale.

Upon a finding that a cardholder has sold cannabis to any person who is not authorized to possess cannabis for medical purposes, the department shall initiate emergency suspension proceedings pursuant to SDCL 1-26-29 and notify the cardholder in writing of the revocation of the registry identification card, along with notice of the right to appeal.

Source: __

General Authority: SDCL 34-20G-72(6)

Law Implemented: SDCL 34-20G-83

44:90:12:06. Revocation of registry identification card for serious or multiple violations.

The department may, pursuant to SDCL chapter 1-26 and SDCL 34-20G-84 revoke a registry identification card upon finding that the cardholder has committed serious or multiple violations of SDCL chapter 34-20G, including:

1. Transferring cannabis to any person who is not authorized to possess cannabis for medical purposes;
2. Submitting false information to the department;
3. Making false statements to a law enforcement officer;
4. Allowing unauthorized use of a registry identification card;

DOH DRAFT RULES

5. Accepting remuneration other than direct costs incurred for assisting with the registered qualifying patient's medical use of cannabis, pursuant to SDCL 34-20G-2(2); or
6. Cultivating cannabis in violation of SDCL chapter 34-20G.

Source: __

General Authority: SDCL 34-20G-72(6)

Law Implemented: SDCL 34-20G-84

CHAPTER 44:90:13

PETITIONS TO RECOGNIZE DEBILITATING MEDICAL CONDIITIONS

Section

44:90:13:01 Petitions – Required forms.

44:90:13:02 Department's decision.

44:90:13:01. Petitions – Required forms.

A petition to the secretary to add a medical condition to the list of debilitating medical conditions for which a practitioner may recommend the medical use of cannabis must be submitted on forms provided by the department. The petition must include:

1. The name and address of the South Dakota resident filing the petition;
2. A clear description of the specific medical condition, defined as narrowly as possible, including any International Classification of Diseases, Tenth Revision (ICD-10) code applicable to the condition;

DOH DRAFT RULES

3. The diagnostic criteria for determining whether cannabis is appropriate for a patient with the medical condition; and
4. A detailed summary, with citations, of peer-reviewed research that treatment with cannabis produces superior treatment outcomes or fewer side effects, compared to currently available medications or other interventions;
5. Letters of support from two physicians currently licensed pursuant to SDCL chapter 36-4; and
6. Complete copies of any research cited in the petition.

Source: _

General Authority: SDCL 34-20G-72(1)

Law Implemented: SDCL 1-26-13 and 34-20G-26

Reference: National Center for Health Statistics. (2021). *International Classification of Diseases, 10th Revision, Clinical Modification.* https://icd10cmtool.cdc.gov/

44:90:13:02. Department's decision.

The secretary's written decision to approve or deny a petition shall be issued within 180 days of submission and shall include the factors supporting the decision, including whether the written petition, public testimony, written comments, peer-reviewed research, and consultation with practitioners support the following conclusions:

1. The proposed medical condition is recognized by the medical profession as a serious and chronic medical condition;

DOH DRAFT RULES

2. Treatments currently available for the proposed condition are either ineffective or produce harmful side effects; and
3. Medical use of cannabis will provide therapeutic or palliative benefits that outweigh the risks of cannabis use.

Source: _

General Authority: SDCL 34-20G-72(1)

Law Implemented: SDCL 34-20G-26

DOH DRAFT RULES