President Pro Tempore Lee Schoenbeck, Chair | Speaker Spencer Gosch, Vice Chair
Reed Holwegner, Director | Sue Cichos, Deputy Director | John McCullough, Code Counsel
500 East Capitol Avenue, Pierre, SD 57501 | 605-773-3251 | sdlegislature.gov

South Dakota Legislature
Legislative Research Council

June 16, 2022

Ms. Doreen Kayser
Department of Health
600 East Capitol Avenue
Pierre, South Dakota 57501

Dear Ms. Kayser:

The Legislative Research Council received proposed rules from the Department of Health on May 25, 2022. In accordance with SDCL 1-26-6.5, the Council reviewed the proposed rules for form, style, clarity, and legality, and now returns them with recommended corrections.

Please find attached:

- Proposed Rules Review Research and Fiscal Checklists;
- The proposed rules with recommended form, style, and clarity corrections;
- Directions for Submitting the Final Draft of the Rules; and
- The Interim Rules Review Committee Rules Presentation Format.

In addition to the recommended corrections to form, style, and clarity included in the proposed rules, the Council identifies the following issues regarding legality:

- ARSD 44:90:01:01(2) defines an "age-restricted cardholder" as a cardholder or nonresident cardholder who is under 18 years of age *or who is enrolled in an elementary, middle, or high school.* The term is subsequently used in other rules sections imposing additional requirements (*see*, ARSD 44:90:02:05, "An age-restricted cardholder shall designate at least one designated caregiver.") The general authority and law implemented citations for both sections do not appear to provide the authority to the department to implement additional restrictions on an individual who is 18 years or older based on school enrollment status. Moreover, SDCL 34-20G-33 specifies the requirements for issuing a registration identification card to a qualifying patient who is younger than 18 years of age. This provision does not envision the same requirements for an individual over 18 on the basis of school enrollment status.
- ARSD 44:90:02:03 specifies that a practitioner is not required to certify a patient if the practitioner "does not believe there is any therapeutic or palliative benefit to the patient by using medical cannabis." Senate Bill 4, effective July 1, removed a practitioner's discretion to certify a patient based on the likelihood of therapeutic or palliative benefit from medical cannabis. The provisions effective on July 1 only require a practitioner to state, on the written certification, that the patient has a qualifying debilitating medical condition or associated symptom. Thus, the section no longer appears relevant as it permits a practitioner to issue certification based on the practitioner's opinion of therapeutic or palliative benefit.

Under SDCL 1-26-4(4), the Department is required to adopt the recommended corrections, subject to an appeal to the Interim Rules Review Committee for the Committee's final determination.

Please do not hesitate to contact me if you have any questions or if you would like to discuss any of the recommendations.

Sincerely,

John R. McCullough
Code Counsel

Enclosures

CC: Joan Adam, Secretary, Department of Health

Legislative Research Council
Proposed Rules Research Review Checklist

Date Proposed Rules Received by LRC:	May 25, 2022
Date Public Hearing Scheduled:	June 21, 2022
Proposed Rules Reviewed by:	Anna Madsen
Fiscal Note Reviewed by:	Joey Knofczynski

"No agency rule may be enforced by the courts of this state until it has been adopted in conformance with the procedures set forth in this chapter." (SDCL 1-26-6.8)

Staff:
Please review the proposed rules and supporting documents and submit them with this completed checklist to the Code Counsel within ten business days from the date the proposed rules are received by the LRC.

KEY

ENTRY:	"[Initials]"	"N/A"	"[Initials]*"
MEANING:	Reviewed by	Not applicable	Edit Recommended or Issue

1. Verify the rules packet includes (SDCL 1-26-4(2)):
   a. The proposed rules: AM
      i. Any incorporated material: N/A
   b. Notice of hearing (Form 6): AM

2. Verify all documents have correct citations to the proposed rules provided in the packet. AM

3. Verify the appropriate departmental secretary, bureau commissioner, public utilities commissioner, or constitutional officer approved the rules process to proceed. (SDCL 1-26-4(1)) AM

4. **If the Department of Social Services is promulgating rules that are mandated by federal statute or regulation, use the DSS Federal Regulations Checklist.**

5. Review proposed rules for:

   a. Form, style, and clarity in accordance with the Administrative Rules Drafting Manual (including all existing language, not just amended language). AM*

      i. Verify the most recent rule is used. (Manual, pg. 5) AM

      ii. Verify all cross-references in text are current. (Manual, pg. 6) AM*

      iii. Verify all affected sections are included. For repealed sections, verify all affected sections are amended. (Manual, pg. 6) AM

      iv. Verify any renumbering of rules is consistent with Administrative Rules Drafting Manual. (Manual, pg. 7) AM

b. Legality, including:

i. Verify the General Authority statute provides rule-making authority (i.e., ". . . shall/may promulgate rules to . . ."). (Manual, pg. 8) AM*

ii. Verify the Law Implemented statute identifies the policy intended to be implemented. (Manual, pg. 8) AM*

iii. If the proposed rule incorporates material by reference, verify the rule describes the exact section or portion of the material. (SDCL 1-26-6.6; Manual, pg. 11) N/A

For incorporated material that is not CFR, USC, Fed. Reg., Stat.:

1. Verify the proposed rule includes a reference note identifying the publication by title, date of publication, author, version/edition and where and at what cost the publication may be obtained. N/A

2. Verify there is a statement attached to the material that includes the agency's name, the section number of the rule that incorporates the material, and the date the proposed rule was served on the LRC. N/A

iv. Verify the proposed rule does not incorporate or reiterate any statutory language other than definitions, and that the agency is not publishing or distributing statutory material. (SDCL 1-26-6.1) AM

v. Verify the proposed rule does not restrict any right or privilege to carry or possess a concealed pistol under SDCL chapter 23-7. (SDCL 1-26-6.10) AM

vi. Verify the agency does not delegate authority to a private association. (S.D. Const. art. III, §§ 23(9), 26) AM

vii. Verify the rule does not allow the agency to circumvent the SDCL ch. 1-26 rulemaking process (e.g., authorizing it to make its own rules). (*See* SDCL 1-26-4, 1-26-6.5, 1-26-6.6, 1-26-38(2)) AM

viii. Verify the rule does not contain the agency's internal processes or policy (e.g., personnel policies) or other matter that is not defined as a rule per SDCL 1-26-1(8). AM

ix. Verify the rule does not incorporate a future rule or regulation, or incorporate future amendments to an existing rule or regulation, of another state or the federal government. (*State v. Johnson*, 84 S.D. 556, 173 N.W.2d 894 (1970)) AM

x. Verify only the rules being changed are included in the packet and that chapter indexes are updated as needed. (Manual, pg. 8) AM

6. Review Notice of Public Hearing (SDCL 1-26-4.1):

a. Verify the LRC received the proposed rules at least 20 days prior to the scheduled public hearing. AM

b. Verify the notice contains a narrative description of the effect of the proposed rule. AM

c. Verify the notice contains the reason for adopting the proposed rule. AM

d. Verify the notice contains the location, date, and time (Central or Mountain) of the hearing. AM

e. Verify the notice contains information about how amendments, data, opinions, and arguments may be presented. AM

f. Verify the notice contains a deadline for submission of comments. AM

i. If the authority promulgating the rule is a secretary, commissioner, or officer, ensure the deadline is ten days after the public hearing. (SDCL 1-26-4(6)) AM

ii. If the authority promulgating the rule is a part-time citizen board, Commission, committee, or task force, ensure the deadline is at least 72 hours before the public hearing (not including hearing day). (SDCL 1-26-4(6)). N/A

g. Verify the notice contains information for how the public may obtain copies of the proposed rules. AM

7. For any proposed rule regarding professional or regulatory examination or licensing that is to be published in pamphlet form, review the pamphlet for style, form, and clarity in accordance with the Administrative Rules Drafting Manual. (SDCL 1-26-11) N/A

Reviewed by Code Counsel on 06/15/2022 JRM

Legislative Research Council
Proposed Rules Fiscal Note Review Checklist

Date Proposed Rules Received by LRC:	June 21, 2022
Date Public Hearing Scheduled:	Anna Madsen
Proposed Rules Reviewed by:	Joey Knofczynski
Fiscal Note Reviewed by:	AM

"No agency rule may be enforced by the courts of this state until it has been adopted in conformance with the procedures set forth in this chapter." (SDCL 1-26-6.8)

Staff:
Please review the proposed rules and supporting documents and submit them with this completed checklist to the Code Counsel within ten business days from the date the proposed rules are received by the LRC.

KEY

ENTRY:	"[Initials]"	"N/A"	"[Initials]*"
MEANING:	Reviewed by	Not applicable	Edit Recommended or Issue

1. Verify the rules packet includes (SDCL 1-26-4(2)):
   a. Fiscal note (Form 5): AM
   b. Small business impact statement (Form 14): N/A
   c. Housing Cost Impact Statement (Form 16), if applicable: AM

2. Review proposed rules for:

   i. If the rule increases a fee, verify the agency provided information regarding financial resources available to the agency: beginning fund balance, receipts, disbursements, and ending fund balance for each of the last two fiscal years, as well as beginning fund balance, projected receipts, projected disbursements, and ending balance for current and next fiscal years. (SDCL 1-26-4.8) AM

   ii. If the rule increases a fee by a licensing board or commission, verify the fee increase is "reasonable and necessary" in accordance with SDCL 1-26-6.9. AM*

3. Review the Fiscal Note (SDCL 1-26-4.2):

   a. Verify the Fiscal Note states whether the proposed rule will have any effect on the revenues, expenditures, or fiscal liability of the state, agencies, and subdivisions: AM

      i. If there is an effect, verify the Fiscal Note includes an explanation of how the effect was computed? N/A

      ii. If there is an effect on subdivisions, is that effect described? N/A

4. Review Small Business Impact Statement (SDCL 1-26-2.1):

a. Verify if the rule change has any small business impact based on readily available info:	AM*
i. If only INDIRECT, verify that a brief description of the impact is included.	AM
ii. If DIRECT, review 4.b through 4.h:	
b. Verify the Impact Statement includes a narrative explanation in plain, easy-to-read language.	AM
c. Verify the narrative explanation discusses the effect of the proposed rule on small business, including the basis for the rule's enactment and why the rule is needed.	AM*
d. Verify the narrative explanation includes an identification and estimated number of small businesses subject to the proposed rule.	N/A
e. Verify the Impact Statement includes the projected reporting and record-keeping required for compliance with the proposed rule.	N/A
f. Verify the Impact Statement includes the types of professional skills necessary for preparation of required reports or records.	AM
g. Verify the Impact Statement includes a statement of the probable effect on impacted small business.	AM
h. Verify the Impact Statement includes a description of any less intrusive or less costly alternative methods of achieving the proposed rule's purpose.	JK

5. Review Housing Cost Impact Statement (SDCL 1-26-2.3), if applicable:

a. Verify that the agency has indicated what building sectors will be impacted by the rule change.	AM
b. Verify a description of and explanation of necessity for each each standard and requirement is included.	AM
c. Verify the statement includes the average estimated cost of each standard and requirement.	AM
d. Verify that contact and estimate information is included for three licensed contractors or building trades professionals.	AM

Reviewed by Code Counsel on 06/15/2022 JRM

ARTICLE 44:90

MEDICAL CANNABIS

Chapter

Commented [AM1]: Style/form: It is not necessary to include the table of contents of an article or chapter if not making any revisions to titles or catchlines.

CHAPTER 44:90:01

DEFINITIONS

Section

44:90:01:01 Definitions.

44:90:01:01. Definitions. Terms defined in SDCL 34-20G-1 have the same meaning when used in this article. As used in this article:

(1) "Action level" means the level of a contaminate that triggers action to prohibit a cannabis product from being sold;

(2) "Age-restricted cardholder" means a cardholder or nonresident cardholder who is under 18 years of age or who is enrolled in an elementary, middle, or high school;

(3) "Agent identification badge" means a credential provided by an establishment for use by an agent while performing work-related duties;

(4) "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)(c); Nothing in these rules applies to drugs approved by the Food and Drug Administration;

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

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

(7) "Authorized transfer" means the distribution of cannabis and cannabis products between medical cannabis establishments that is allowable within inventory tracking system procedures;

Commented [AM2]: Legality: This phrase indicates that a cardholder who is 18 or older, but is enrolled in high school, would be an age-restricted cardholder. SDCL 34-20G-72, the general authority and law implemented citation, does not seem to provide for additional restrictions for someone who is over 18 based on enrollment status. SDCL 34-20G-33 only specifies restrictive provisions for a qualifying patient younger than 18.

Commented [AM3]: Clarity/legality: Is the intent to include both subsections (b) and (c)? If so, the drafting convention provided in the Adminstrative Rules Drafting Manual on pg. 20 would be: "SDCL subsections 34-20G-1(1)(b) and (c)." The in-text drafting convention is different than the general authority and law implemented convention.

If the intent is only subsection (c), when amending a citation, the entire citation should be struck and replaced, even when only modifying a subdivision or subsection. ARSD Drafting Manual, pg. 5-6.

Commented [AM4]: Clarity: Since this is part of a definition, the language should be specific to the term. Otherwise, the rule is setting forth substantive language and would not belong in a definitions section. ARSD Drafting Manual, pg. 10. Perhaps: "This term does not apply to drugs approved by the Food and Drug Administration;"

Commented [AM5]: Style/form: Abbreviations should first be spelled out and then followed by abbreviation in parenthesis if used multiple times. This appears to only be used once. ARSD Drafting Manual, pg. 13.

(8) “Batch” means a specific quantity of cannabis that is the same strain, grown under the same conditions, and harvested during a specified period of time from a specified cultivation area within a cultivation facility, with the exception of trim; or a specific quantity of cannabis products that is produced during a specified period of time using the same extraction and/or manufacturing method, formulation, and/or recipe;

(9) “Batch identifier” means a unique number or code assigned by an establishment to a quantity of cannabis or cannabis products for testing;

~~(8)~~(10) “Cannabis beverage” means a liquid edible cannabis product with a concentration of less than one milligram of delta-9 tetrahydrocannabinol (THC) per ounce of liquid;

~~(9)~~(11) “Cannabis extract” means the resin extracted from any part of a cannabis plant using a liquid or gaseous solvent other than water;

~~(10)~~(12) “Cannabis oil” means an edible cannabis product using a food-safe oil as the primary noncannabis ingredient and with no added flavors, colors, o+r scents;

(13) “Cannabis testing facility designee” means an employee or an agent of the cannabis testing facility ~~that~~ who holds an agent identification badge and has completed the required training for the purposes of sample collection;

~~(11)~~(14) “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 have been designated for destruction;

~~(12)~~(15) “Certificate of analysis” means a written report of the results of analytical testing, indicating whether the results comply with this article;

~~(13)~~(16) “Chain of custody” means documentation of the handling of cannabis and cannabis products;

Commented [AM6]: Style/form: "and/or" is not used as a drafting convention. The recommended usage is "either A or B, or both,". Perhaps "or" would suffice for this list? ARSD DM, pg. 22.

Commented [AM7]: Style/form: Oxford comma is used. ARSD DM, pg. 17.

Commented [AM8]: This looks like a typo.

~~(14)~~(17) “Collective” means two or more cardholders who physically assist each other in the act of cultivating or processing cannabis for medical use, except that the sharing of an enclosed, locked facility for cultivation by two or more cardholders in their own dwelling is not a collective;

~~(15)~~(18) “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;

~~(16)~~(19) “Concentrated cannabis” or “cannabis concentrate” means cannabis extract or a preparation made by using heat, temperature, or mechanical means to separate cannabinoids from cannabis, including hashish;

~~(17)~~(20) “Confirmation testing” means testing performed by, or at the direction of, the department to determine consistency and accuracy of tests offered by cannabis testing facilities;

~~(18)~~(21) “Equivalent cannabis weight” means the weight, in ounces, that a given quantity of cannabis product counts against the total allowable amount of cannabis under SDCL 34-20G-1(1);

~~(19)~~(22) “Exit packaging” means a bag, box, or other container for use in transporting cannabis or cannabis products after purchase at a dispensary;

~~(20) “Extended plant count” means the authorized cultivation of more than three plants simultaneously for a single patient’s use;~~

~~(21)~~(23) “Flower” means the pistillate reproductive organs of a mature cannabis plant, whether processed or unprocessed, including the flowers and buds of the plant;

(24) “Homogenous” means uniform throughout as it relates to the creation of batches and representative sampling. See representative sampling definition;

Commented [AM9]: Clarity: Is "homogenous" being used in a different context than the commonly understood definition? It appears to me that it is used simply used as an adjective for other defined terms. There is no additional information as to what "uniform throughout" means or is measured. With the recommendation below to simply use "representative sample" instead of "homogenous sample", is this definition necessary?

Commented [AM10]: Clarity: This is redundant language and recommend it be removed. Also note that the definition is "sample" and not "sampling".

~~(22)~~(25) "Immature plant" means a nonflowering cannabis plant that measures 12 inches or more from the base of the main plant stalk to the most distant point of the plant's leaf stems or branches;

~~(23)~~(26) "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;

~~(24)~~(27) "Inhalable cannabis product" means a cannabis product that is intended to be consumed by inhalation;

~~(25)~~(28) "Inherently hazardous substance" means any solvent or chemical, other than ethanol, with a flash point at or lower than 100 degrees Fahrenheit;

~~(26)~~(29) "Inventory record" means a daily electronic record of all cannabis;

~~(27)~~(30) "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 or cannabis products;

~~(28)~~(31) "ISO/IEC 17025 accreditation" means accreditation by the International Accreditation Service, the American Association for Laboratory Accreditation, the American National Standards Institute's National Accreditation Board, or another laboratory accreditation board that the testing facility meets *General Requirements for the Competence of Testing and Calibration Laboratories* developed by the International Organization for Standardization and the International Electrotechnical Commission for a particular analyte and technology;

~~(29)~~(32) "Low-income" means having a gross monthly household income that is 130 percent or less of the federal poverty level as defined by § 67:11:01:03;

~~(30)~~(33) "Marketing layer" means the outermost layer of a retail sale container predominantly apparent and visible;

~~(31)~~(34) "Matrix" means a component or substrate that contains an analyte being tested for;

~~(32)~~(35) "Mature plant" means a cannabis plant that has flowered;

~~(33)~~(36) "Nationally recognized testing laboratory" means an independent laboratory recognized by the Occupational Health and Safety Administration pursuant to 29 C.F.R. § 1910.7 (February 18, 2020);

~~(34)~~(37) "Nonusable" means unfit for sale or, except for the purposes of remediation, transfer;

~~(35)~~(38) "Remediation" means the further processing of a batch of cannabis or cannabis products that has failed testing, using a process approved by the department to address the reasons for the failure;

(39) "Representative sample" means the amount of cannabis and cannabinoids within the product being consistent and reasonably equally dispersed throughout the product or each portion of the product~~, or a homogenous sample~~.

~~(36)~~(40) "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;

~~(37)~~(41) "Seedling" means a nonflowering cannabis plant or rooted cutting that measures less than 12 inches from the base of the main plant stalk to the most distant point of the plant's leaf stems or branches;

~~(38)~~(42) "Smokable form" means in a form of cannabis or cannabis product marketed to be heated in the presence of oxygen and inhaled through smoking;

Commented [AM11]: Clarity: I do not see "homogenous sample" used anywhere in this rule. Only one term should be used to avoid confusion.

Commented [AM12]: Style/form: This should be a semicolon.

~~(39)~~(43) “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;

~~(40)~~(44) “Testing sample record” means a daily electronic record maintained by an establishment of batch identifiers, sample identifiers, and associated information;

~~(41)~~(45) “Tincture” means a liquid edible cannabis product with a concentration of greater than one milligram of THC per ounce of liquid in the form of ethanol, propylene glycol, glycerin, or food safe oil;

~~(42)~~(46) “Topical cannabis product” means a nonedible cannabis product that is intended to be applied externally to the skin;

~~(43)~~(47) “Transaction record” means a daily electronic record created and maintained by a dispensary to track transactions with patients;

~~(44)~~(48) “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;

~~(45)~~(49) “Trim” means trichome-containing leaves of the cannabis plant that have been intentionally removed during cultivation; and

~~(46)~~(50) “Vaporizer product” means an inhalable cannabis product containing concentrated cannabis that is heated below the point of combustion.

Source: 48 SDR 40, effective October 5, 2021.

General Authority: SDCL 34-20G-72.

Law Implemented: SDCL 34-20G-72.

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. Cost: $138.

Commented [AM13]: Clarity: Although I understand this is likely from the hyperlink, this appears to already be in the rule, and thus should not be underscored.

Cross-Reference: Federal poverty level, § 67:11:01:03.

CHAPTER 44:90:02

REGISTRY IDENTIFICATION CARDS

Section

44:90:02:05 Patient designation of designated caregivers -- Age-restricted cardholders -- Person responsible for making medical decisions -- Residents of health care facility or residential care facility.

44:90:02:06 Designated caregivers -- State-only background check -- Prohibition of remuneration.

44:90:02:07 Application to cultivate cannabis -- Patient designation of designated caregivers to cultivate cannabis.

44:90:02:08 Requirements for designated caregivers designated to cultivate cannabis.

44:90:02:09 Registry identification card -- Renewal.

44:90:02:10 Change of designation of designated caregivers.

44:90:02:11 Change of designation to cultivate.

44:90:02:12 Notice to no longer act as designated caregiver.

44:90:02:13 Death of a qualifying patient.

44:90:02:14 Nonresident registration -- Required documentation.

44:90:02:15 Nonresident registration -- Registry identification number.

44:90:02:16 Allowable quantity of cannabis products.

44:90:02:16.01 Limits on inhalable cannabis products.

44:90:02:17 Fees for registry identification cards.

44:90:02:01. Practitioner's written certification of debilitating medical condition ~~and therapeutic or palliative benefit~~. Only a practitioner as defined by SDCL ~~34-20G-1~~(20)~~(21)~~ subdivision 34-20G-1(21) may issue a written certification pursuant to SDCL subdivision 34-20G-

Commented [AM14]: Style/form/clarity: Generally, cross-referencing subdivisions is avoided so as not to necessitate updating references if the list is amended. Unless the use of a subdivision is necessary to avoid confusion, it is acceptable to use the section as the cross-reference. In this case, I think SDCL 34-20G-1 suffices as it is obvious where "practitioner" is defined in that list.

Either way, as noted in a comment above, the full citation should be struck and the new inserted. The drafting convention for citing subdivisions, if they are retained: "SDCL subdivision ..." as demonstrated here. ARSD DM, pg. 20.

Commented [JM15R14]: In the alternative, since the definition in SDCL 34-20G-1 apply to this article, the reference can be overstricken/deleted.

1~~(23)~~(26) to a resident of South Dakota. A practitioner's written certification shall be submitted to the department and must be on a form supplied by the department. The certification must include:

(1) The practitioner's name and address;

(2) The practitioner's South Dakota license and National Practitioner Identification numbers, if applicable;

(3) Certification that the practitioner has assessed the patient's medical history and current medical condition, including an in-person physical examination;

(4) The date on which the physical examination was conducted;

(5) Certification that the patient has a debilitating medical condition, as defined by SDCL 34-20G-1(8), specifying the International Classification of Diseases, Tenth Revision code;

(6) Certification that the practitioner and patient, or the patient's parents or legal guardian, have discussed treatment options for the patient's debilitating medical condition~~, including the therapeutic or palliative benefits and risks associated with the medical use of cannabis~~;

(7) Certification that the practitioner is available for further consultation and follow-up care with the patient or the patient's parents or legal guardian ~~as required~~ to monitor the medical use of cannabis;

(8) The date~~, if applicable, on which the patient's need for the medical use of cannabis is expected to end; and~~ of expiration, not to exceed one year;

(9) The number of designated caregivers, if more than one, that the patient's age or medical condition necessitates; and

(10) Certification that ~~the~~ a bona-fide practitioner-patient relationship exists and the relationship is not for the sole purpose of providing a written certification for medical cannabis, unless referred by another practitioner.

Commented [AM16]: Style/form: This subdivision I would recommend keeping, but noting the partial citation amendment here.

Commented [JM17]: The written certification is defined in SDCL 34-20G-1. It is not issued pursuant to a definition. I think the reference to SDCL 34-20G-1 can be overstricken/deleted.

Commented [AM18]: Style/form: The comma after "condition" should be struck and this semicolon should be retained.

Formatted: Not Strikethrough

Commented [AM19]: Style/form: This should be hyphenated as it is a compound modifier. ARSD DM, pg. 17.

Commented [AM20]: Style/form: This term is not hyphenated in chapter 34-20G.

Commented [JM21]: This portion of the sentence seems to be a restatement of a portion of the definition of bona-fide practitioner-patient relationship found in SDCL 34-20G-1(2)(d). Can it be removed?

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-1(2), 34-20G-1~~(23)~~(26), 34-20G-29.

Commented [AM22]: Style/form: Please see previous comment about amending partial citations.

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

Commented [AM23]: Style/form: I understand the underscore here is probably from the hyperlink, but it should be removed as it indicates this is new material being added, when this is already in the rule.

44:90:02:02. Practitioner's written certification -- Determination of caregivers. For patients under the age of 18, a practitioner as defined by SDCL 34-20G-1~~(20)~~(21) shall consult with the patient's parents or legal guardians to determine how many designated caregivers are needed to manage the acquisition, dosage, and frequency of use. The practitioner shall include the number of designated caregivers on the written certification.

Commented [AM24]: Clarity: Is this language necessary since "practitioner" is already defined in SDCL 34-20G-1 and the terms defined there mean the same as in this article per 44:90:01:01?

For patients 18 years of age or older, if the practitioner believes the patient's age or medical condition necessitates the appointment of more than one designated caregiver, the practitioner shall include the number of designated caregivers on the written certification.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-29.

Commented [AM25]: Legality: SDCL 34-20G-33 might also be an appropriate law implemented since it relates to the practitioner and designated caregiver process for those under 18.

44:90:02:02.01. Practitioner certification -- Recommendation for cultivation of cannabis -- Extended plant count. ~~The department shall reject a recommendation for a South Dakota resident to cultivate an extended plant count not issued by a physician. The physician's recommendation that the patient be allowed to cultivate an extended plant count expires 200 days after the date of the recommendation.~~

~~A physician's recommendation for an extended plant count must specify the following reasons for the extended plant count:~~

~~(1) The research on which the physician 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;~~

~~(2) 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; and~~

~~(3) Any other factors justifying the recommendation~~ Repealed.

Source: 48 SDR 54, effective November 15, 2021.

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

~~**Law Implemented:** SDCL 34-20G-1(1)(c), 34-20G-29, 34-20G-72(5).~~

44:90:02:03. Practitioner not required to provide certification. Nothing in this chapter requires a practitioner as defined by SDCL 34-20G-1~~(2)20~~(21) to certify a patient for medical cannabis use if ~~they do~~ the practitioner does not believe there is any therapeutic or palliative benefit to the patient by using medical cannabis.

Commented [AM26]: Clarity: See previous comments about redundancy of this phrase.

Commented [AM27]: Clarity/legality: With the passage of Senate Bill 4, which removed the practitioner's authority to provide a certification on the likelihood of the patient's therapeutic or palliative benefit, is this section still relevant?

Commented [JM28R27]: Should the section just be repealed?

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-29.

44:90:02:05. Patient designation of designated caregivers -- Age-restricted cardholders -- Person responsible for making medical decisions -- Residents of health care facility or residential care facility. A qualifying patient may designate an eligible individual as a designated caregiver by submitting to the department:

(1) A completed designation on a form supplied by the department;

(2) The designated caregiver's sworn statement that the designated caregiver has not been convicted of a disqualifying felony offense; and

(3) Any additional fees pursuant to § 44:90:02:17.

An age-restricted cardholder shall designate at least one designated caregiver. If a practitioner has recommended that a patient younger than 18 years of age have multiple designated caregivers, the parents or legal guardians may designate other designated caregivers as advised by the practitioner.

The person responsible for making medical decisions for a qualifying patient 18 years of age or older, if qualified pursuant to SDCL 34-20G-1(10), shall be the designated caregiver to the qualifying patient. If the practitioner has recommended that the patient have multiple designated caregivers, the person responsible for making medical decisions may designate other designated caregivers as advised by the practitioner.

The designation of an employee of a health care facility ~~or residential care facility~~, as defined in SDCL 34-12-1.1;~~,~~ an accredited prevention or treatment facility, as defined in SDCL 34-20A-

Commented [AM29]: Legality: This statute does not provide a policy, standard, or rule that limits the agency from exercising unlimited or absolute discretion in its power to adopt a particular rule. This section only relates to information a patient must submit to the department for the issuance of registration cards, not the discretion of a practitioner to refuse written certification to a patient.

Commented [AM30]: Clarity: This catchline needs to be updated given the addition of entities.

Commented [AM31]: Legality: Please see previous comment about "age-restricted cardholder."

Commented [AM32]: Clarity: These changes are suggested to reflect SB 19 as appears to be the intent. Also, semicolons may help to clarify each facility of the list.

2~~,~~; a mental health center, as defined in SDCL 27A-1-1~~,~~; a child welfare agency, as defined in SDCL 26-6-1~~,~~; or a community support provider or community services provider, as defined in SDCL 27B-1-17; to act as a designated caregiver on the premises of the facility requires the signature of the facility director or designee.

The designation of a designated caregiver expires on the same date as the qualifying patient's registry identification card.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL ~~SDCL~~ 34-20G-1(10), 34-20G-2(2), 34-20G-29, 34-20G-30, 34-20G-32, 34-20G-33, 34-20G-35, ~~34-20G-39~~, 34-20G-95.

Commented [AM33]: Legality: This statute does not seem to be related to this section.

44:90:02:06. Designated caregivers -- State-only background check -- Prohibition of remuneration. Each person designated as a designated caregiver to one or more qualifying patients shall submit to the Division of Criminal Investigation once every two years:

(1) A photocopy of an unexpired form of identification acceptable for voter identification pursuant to SDCL 12-18-6.1;

(2) A Division of Criminal Investigation fingerprint card processed by a local law enforcement agency; and

(3) 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.

A designated caregiver shall submit to the department a photograph meeting the requirements of § 44:90:02:04(3) once every five years. A designated caregiver shall acknowledge

in writing to the department 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).

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-1(10), 34-20G-2(2), 34-20G-29, 34-20G-30, 34-20G-32, 34-20G-33, ~~34-20G-39~~.

44:90:02:08. Requirements for designated caregivers designated to cultivate cannabis. Only one person may cultivate cannabis on behalf of a patient, except that:

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

(2) Two parents or legal guardians of an age-restricted cardholder who reside in the same dwelling may share the designation.

The entirety of a patient's cannabis must be cultivated in a single enclosed, locked facility. ~~No designated caregiver may simultaneously cultivate an extended plant count for more than one qualifying patient.~~

Two or more designated caregivers may not form a collective. Two or more designated 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: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-1(13), 34-20G-29.

CHAPTER 44:90:03

REGISTRATION CERTIFICATES

Section

44:90:03:07. Cannabis testing facility operating procedures -- Additional requirements. The written operating procedures for a testing facility must provide the department with sufficient detail to determine the establishment's compliance with this article and SDCL chapter 34-20G, including:

(1) A policy signed by each owner that 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, judgment, or operational integrity;

(2) A signed disclosure by each owner 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 list of analytical tests, specifying the analyte and technology for each, the applicant intends to offer and:

(a) Certification that the applicant will, within six months of licensing, begin 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) If an initial application or a renewal application for a cannabis testing facility that has been licensed for less than 18 months, an agreement to:

(i) Submit quarterly reports to the department on its progress toward ISO/IEC accreditation; and

(ii) Comply with any department requests for confirmation testing at the cannabis testing facility's expense;

(4) Standard operating procedures for all preanalytical, analytical, and post-analytical processes performed by the laboratory;

(5) Protocols for performing validation studies of all analytical tests to be performed;

(6) Protocols for proficiency testing at an interval determined by the accrediting body and documenting successful completion or corrective action, as defined by the accrediting body;

(7) A program to assess and document, at least annually, the competency of all technical and scientific staff that perform preanalytical, analytical, and postanalytical processes;

(8) 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;

(9) Policies and procedures for collection and receipt of samples for mandatory or other testing, including:

(a) Step-by-step procedures for collecting samples from each matrix type that are representative of the batch to be tested;

Commented [AM34]: Clarity: Does this now fit under the definition of "representive sample"? If so, recommend this subdivision be rephrased using the definition.

(b) Method for collection, preparation, packaging, labeling, documentation, and transport of samples from each matrix type;

(c) Size of sample to be collected for each analytical test to be performed;

(d) Safeguards against contamination, including protective garb, sanitizing of instruments, and care of sample collection containers;

(e) Labeling of sample containers; and

(f) Transport and storage conditions, including exposure to light, temperature, and humidity;

(10) Chain of custody protocols and a sample chain of custody form; ~~and~~

(11) Training procedures and records of training for all cannabis testing facility designees to be maintained on the premises; and

~~(11)~~(12) Equipment to be used and its listing by a nationally recognized testing laboratory.

Source: 48 SDR 40, effective October 5, 2021.

General Authority: SDCL 34-20G-72(2)(5).

Law Implemented: SDCL ~~SDCL~~ 34-20G-55(1), 34-20G-72(5).

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. Cost: $138.

Commented [AM35]: Style/form: Noting the underscore here with the hyperlink. See previous comment.

CHAPTER 44:90:04

ESTABLISHMENTS

Section

44:90:04:17 Security protocols -- Training requirements.

44:90:04:18 Vehicle requirements -- Establishments.

44:90:04:19 Transport manifests -- Form and content.

44:90:04:20 Separate transport manifest required.

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.

44:90:04:13. Controlled access -- Verification of identity. No medical cannabis establishment may share premises with or permit access directly from any residence or business unless permitted by § 44:90:04:04. This section ~~shall~~ may not be interpreted to prohibit access from a shared parking lot, walkway, concourse, or other area generally open to the public as part of a shopping center or business park.

Commented [AM36]: Style/form: "May not" indicates a prohibited action. ARSD DM, pg. 14-15.

A medical cannabis establishment shall verify the age and identity of ~~anyone~~ any person entering the premises by requiring the person to present a valid photographic identification document issued by this state, another state, tribe, or the federal government. Unless permitted by SDCL 34-20G-65 or § 44:90:08:01, no person may enter the premises other than agents of the establishment, contractors 18 years of age or older hired by the establishment, employees or agents of the department, law enforcement officers, or 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: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-65, 34-20G-69, 34-20G-72(5).

44:90:04:16. Record-keeping -- Use of inventory tracking system -- Training requirements. Prior to performing duties onsite or transporting cannabis, an establishment agent shall receive at minimum two hours of training in record-keeping. The agent's training must be documented in the establishment's records.

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. At least one establishment agent for each establishment shall receive at minimum four hours of training to act as an administrator of the inventory tracking system.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5).

44:90:04:19. Transport manifests -- Form and content. A transport manifest is required for all authorized transfers of any amount of cannabis or cannabis products, except retail sales at a dispensary. The transport manifest must contain:

(1) The name, address, phone number, and license number of the medical cannabis establishment transporting the cannabis or cannabis products;

Commented [AM37]: Legality: This subsection does not seem to be an accurate general authority--it relates to employment and training requirements. Would (c) be more appropriate as it relates to security requirements?

Commented [AM38]: Clarity: Should this be "medical cannabis establishment agent", as defined in SDCL 34-20G-1(17)?

(2) The name, address, phone number, and license number of the establishment receiving the items;

(3) The phone number and web address of the department's secure verification system;

(4) Description and quantities, either by weight or unit, of all items, including samples, contained in each transport;

(5) Date of transport and approximate time of departure and arrival;

(6) Vehicle make, model and license plate number;

(7) The name and signature of driver and any other agent accompanying the transport; and

(8) The name and signature of the person accepting the transport, upon delivery.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63.

44:90:04:20. Separate transport manifest required. A separate transport manifest shall be prepared for each medical cannabis establishment that will receive cannabis or cannabis products. The vehicle must carry three copies of each transport manifest:

(1) One for the recipient;

(2) One to be returned to the originating establishment for the purposes of record keeping; and

(3) 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.

Any cannabis or cannabis products, including samples, that are refused by the intended recipient must be noted on the transport manifest and noted in the originating establishment's inventory records after the items are returned.

A transport manifest may not be altered from the originating establishment except as provided for in this section.

The transport manifest does not take the place of a chain-of-custody form that may be required of the establishment.

Source: 48 SDR 40, effective October 5, 2021.

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

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

44:90:04:21. Storage during transport. All cannabis or cannabis products being transported must be contained within an enclosed, locked area in the transport vehicle and out of public view. Samples of cannabis and cannabis products for testing must be transported in appropriately labeled sample collection containers with tamper-evident seals affixed that provide clear, lasting evidence that the package has previously been opened. All cannabis or cannabis products being transported to another medical cannabis establishment, other than samples for testing, must be transported within sealed containers identifying the recipient.

A cannabis product manufacturing facility or dispensary transporting any edible product requiring refrigeration to another establishment shall provide refrigerated transport. An establishment shall use temperature-controlled transport vehicles when necessary to prevent spoilage of the transported cannabis or cannabis products.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-64, 34-20G-72(5).

44:90:04:22. Conduct during transport. Only agents of the medical cannabis establishment who are listed on each transport manifest may be in the vehicle. Each agent shall wear an agent identification badge while in the vehicle. Any vehicle transporting cannabis or cannabis products shall travel directly to the destinations listed on transport manifest, making stops only:

(1) For meals, when the transport lasts more than three hours round trip;

(2) For rest periods required by law;

(3) To refuel; or

(4) Under exigent circumstances, including collisions, traffic stops, mechanical breakdowns, weather emergencies, or medical emergencies.

An agent may not remove the cannabis 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 pursuant to §44:90:04:23.

An establishment agent shall make a vehicle used for the transport of cannabis or cannabis products immediately available for inspection upon request of the department.

Upon law enforcement contact, agents shall provide their agent identification badges and all transport manifests.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-64, 34-20G-72(5).

44:90:04:23. Transport incident notification. Any traffic stop, breakdown, collision, or unscheduled stop lasting more than two hours involving a vehicle being used by ~~an~~ a medical cannabis establishment to transport cannabis or cannabis products, must be reported to the department within one business day. Any theft or break-in involving a vehicle being used by an establishment to transport cannabis or cannabis products must be reported to local law enforcement and to the department within one business day.

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 a good faith effort to protect the shipment from diversion.

Commented [AM39]: Clarity: "or cannabis products"?

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-64, 34-20G-72(5).

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 protect against damage from light, water, insects, or rodents; and

(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: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-64, 34-20G-72(5).

CHAPTER 44:90:06

CANNABIS TESTING FACILITIES

Section

44:90:06:09 Results of confirmation testing.

44:90:06:03. Sample collection. Each cannabis testing facility shall adopt standard operating procedures for the collection of samples for testing that must address:

~~(1) Minimum and maximum batch size for cannabis and cannabis products;~~

~~(2)~~(1) Standards for the assignment of batch identifiers and sample identifiers;

~~(3)~~(2) Minimum quantity of cannabis and cannabis products needed for each analytical test;

~~(4)~~(3) Methodology for collecting material that is representative of the entire batch being tested;

~~(5)~~(4) Cleaning, sanitizing, and other methods for preventing sample contamination;

~~(6)~~(5) Containers to be used for sample collection, including methods for sealing; and

~~(7)~~(6) Prevention of damage or degradation during storage and transport.

Source: 48 SDR 40, October 5, 2021.

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

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

44:90:06:05. Chain of custody protocols. The chain of custody protocols developed by a cannabis testing facility must be approved by the department and must address:

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

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

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

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

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5).

44:90:06:06. Chain of custody -- Form. The chain of custody form must include:

(1) The sample location;

(2) The number and types of containers;

(3) The mode of collection;

(4) The authorized individual who collected the sample;

(5) The date and time of collection; and

(6) The requested analyses.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5).

44:90:06:07. Reporting of test results. The results of any analytical test of cannabis or cannabis products shall be provided to the cannabis cultivation facility or cannabis product manufacturing facility in the form of a certificate of analysis.

The cannabis testing facility shall update, each day by midnight, the inventory tracking system with:

(1) All samples collected; and

(2) The results of all voluntary and mandatory tests performed, including as applicable a quantitative value and whether the sample has passed or failed the test.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5).

CHAPTER 44:90:08

CANNABIS DISPENSARIES

Section

44:90:08:03. Preventing unauthorized sales -- Training requirements. Before interacting with any cardholder, any employee of a dispensary shall be trained to:

(1) Determine the authenticity of registry identification cards;

(2) ~~Ensure~~ Verify that the person presenting a registry identification card is the authorized cardholder with a valid photographic identification document;

(3) Use the verification system by phone, point-of-sale software, and mobile application;

(4) Track the amount of cannabis dispensed for a patient's use and consolidate the amounts in sales to the patient and the patient's designated caregiver; and

(5) Verify that the dispensary has been designated to make sales to the patient or the patient's designated caregiver.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-70, 34-20G-71, 34-20G-72(5).

CHAPTER 44:90:09

SAMPLING AND TESTING

Section

44:90:09:01. Mandatory testing prior to transfer for retail sale. A cultivation facility or cannabis product manufacturing facility must ~~submit cannabis and cannabis products for the following tests prior to transfer to another establishment~~ test every batch of cannabis or cannabis product intended for consumption by a patient or non-resident card holder prior to transfer for retail sale.

The following tests are required for cannabis and cannabis products prior to transfer for retail sale:

Commented [AM40]: Clarity: This is technically the full term defined in SDCL 34-20G-1(4).

Commented [AM41]: Clarity: The term, as defined in statute. is "nonresident cardholder." (no hyphen and cardholder=one word). However, is that distinction redundant? Could it simply be "intended for consumption" or human consumption?

(1) Beginning July 1, 2022:

(a) Potency testing for THC content and, if so labeled, CBD content; and

(b) Microbials listed in §44:90:05:10(3);

(2) Beginning July 1, 2023:

(a) Mycotoxins listed in §44:90:05:10(2);

(b) Metals listed in §44:90:05:10(4) and 44:90:07:03;

(c) Pesticides listed in §44:90:05:10(1); and

(d) Solvents listed in §44:90:07:03.

Source: 48 SDR 40, effective October 5, 2021.

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

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

44:90:09:03. Prohibited transfer of cannabis or cannabis product -- Exceptions. Except as allowed by § 44:90:09:11, no cannabis or cannabis products may be transferred by a ~~cannabis~~ cultivation facility or cannabis product manufacturing facility to a ~~cannabis product manufacturing facility or cannabis~~ dispensary unless:

(1) A cannabis testing facility has performed all mandatory tests on the cannabis or cannabis products and determined it complies with this article; and

(2) The cannabis or cannabis products are accompanied by a certificate of analysis issued by the cannabis testing facility that covers all mandatory tests.

Commented [AM42]: Clarity: Changes made to reflect definitions in statute.

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 is nonusable and may not be remediated.

Source: 48 SDR 40, effective October 5, 2021.

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

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

44:90:09:04. Retention of certificate of analysis. A cannabis product manufacturing facility or cannabis dispensary shall maintain the certificate of analysis for any cannabis or cannabis products for 180 days or until all of the cannabis or cannabis products have been transferred or destroyed, whichever is later.

Commented [AM43]: SDCL 34-20G-1(15) defines "medical cannabis dispensary" or "dispensary." Recommend choosing one of the defined terms.

Source: 48 SDR 40, effective October 5, 2021.

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

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

44:90:09:05. Payment of fees associated with testing. The medical cannabis establishment submitting the cannabis or cannabis products for testing shall pay all fees associated with testing.

Source: 48 SDR 40, effective October 5, 2021.

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

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

44:90:09:06. Creation of batches. A ~~cannabis~~ cultivation facility or cannabis product manufacturing facility shall:

(1) Divide cannabis ~~or cannabis products into batches as directed by a registered cannabis testing facility~~ into batches not to exceed 50 pounds, and as directed by a ~~registered~~ cannabis testing facility;

(2) Divide cannabis products into homogenous batches as directed by a ~~registered~~ cannabis testing facility, and in accordance with the following size limitations:

(a) Cannabis product batches containing concentrated cannabis may not exceed 50 pounds (22.7 kilograms); and

(b) Cannabis product batches containing cannabis extract or products that are infused with cannabis or cannabis extract may not exceed 70,000 unpackaged retail servings;

~~(2)~~(3) Assign a unique batch identifier to the cannabis or cannabis products; and

~~(3)~~(4) When cannabis is harvested or trimmed:

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

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

A batch may be divided into multiple containers. ~~Should~~ If a cannabis or cannabis product yield ~~be~~ is in excess of the batch size limitations, the yield must be divided into separate batches in accordance with this section in order to be sampled. With the exception of trim, all cannabis and cannabis products in each batch must be uniform throughout.

Commented [AM44]: Clarity: Why is "homogenous" used in subdivision (2) to refer to batches for cannabis products but not here?

Commented [AM45]: Clarity: The definition of "cannabis testing facility" already states that the facility is registered with the department, so this is redundant.

Source: 48 SDR 40, effective October 5, 2021.

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

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

44:90:09:07. Collection of samples. A cannabis ~~cultivation facility or cannabis product manufacturing facility shall submit~~ testing facility ~~or a~~ designee ~~of a cannabis testing facility~~ shall collect representative samples for laboratory testing ~~at minimum one sample~~ from each batch of cannabis or cannabis products created pursuant to § 44:90:09:06 ~~or as directed by the cannabis testing facility based on batch size~~.

~~Before January 1, 2024, samples for testing shall be collected by an agent of either the testing facility or the establishment submitting the sample, if:~~

~~(1) No agent collects samples prior to receiving full training on the cannabis testing facility's sample collection procedures;~~

~~(2) The collection of samples takes place in full view of security cameras; and~~

~~(3) The collection of samples by agents of the establishment submitting the samples is done with the permission of the cannabis testing facility. The cannabis testing facility may revoke the permission at any time without stating a reason.~~

~~[On or after January 1, 2024, samples for testing must be collected by an agent of the testing facility.~~

A ~~designee of a~~ cannabis testing facility designee may only collect samples on behalf of a cannabis testing facility upon completing the following requirements:

(1) Obtain a valid agent identification card issued by the testing facility;

Commented [AM46]: Clarity: Isn't the "cannabis testing facility designee," as set out in the proposed definition in 44:90:01:01(13), the only person trained to collect samples?

Commented [AM47]: Clarity: The following list pertains to the training and requirements of being a cannabis testing facility designee--not the collection of samples as the catchline indicates. I would suggest adjusting the catchline to reflect that. Moreover, an employee/agent is not a "designee" until they complete these requirements, as the definition of designee suggests. I would recommend rephrasing this lead-in to something like: "An employee or agent of a cannabis testing facility must complete the following requirements to become a cannabis testing facility designee:...

Ideally, the training and requirements of being a designee would be in separate section rather than in the one for the process of collecting of samples.

(2) Confirm physical ability to perform sample collection procedures and activities;

(3) Complete no less than 10 hours of initial training on sample collection procedures that are in accordance with this chapter, provided by the cannabis testing facility ~~and in accordance with this Chapter~~; and

(4) Demonstrate competency in sample collection in compliance with the cannabis testing facility's sample collection procedures and this ~~Chapter~~ chapter.

A ~~designee of a~~ cannabis testing facility ~~is required to~~ designee must attend no less than 10 hours of continuous training ~~throughout~~ each year in addition to the initial training requirements.

Prior to performing sample collection for mandatory tests, the ~~designee of a~~ cannabis testing facility designee shall contact the testing facility to obtain instructions for each sampling event, including the instruments to be used, the containers required to store samples, storage and transportation requirements, and the receipt and recordkeeping of the samples.

The collection of samples must comply in all manner with ~~§§ 44:90:09:07~~ this section and § 44:90:09:09, the testing facility's standard operating procedures and sample collection procedures, and requirements for ISO/IEC 17025 accreditation.

Source: 48 SDR 40, effective October 5, 2021.

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

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

Reference: International Organization for Standardization & International Electrotechnical Commission. (2018). *ISO/IEC 17025:2017: General Requirements for the Competence of*

Commented [AM48]: Clarity: "Testing facility" is used above. Recommend using consistent term.

Commented [AM49]: Clarity: Suggestion to make clear that the subject of the training material must be in accordance with this chapter.

Commented [AM50]: Clarity: Continuous training on what and provided by who?

Commented [AM51]: Clarity: Using the conjunction "and" indicates only these two sections. Was "through" meant instead to indicate a range?

Testing and Calibration Laboratories. https://www.iso.org/standard/66912.html. Cost: $138.

44:90:09:07.01. Requirements for samples of cannabis and cannabis products. With the exception of pre-rolls, all cannabis and cannabis products must be in final form ready to be packaged upon receipt of passing results for all required tests in order to be sampled. A cannabis cultivator or cannabis product ~~manufacturer~~ manufacturing facility may not alter the cannabis or cannabis product batch after sampling has occurred.

The cannabis testing facility or ~~a designee of~~ a cannabis testing facility designee ~~must~~ shall sample the amount of cannabis and cannabis products and increments in accordance with the tables below, in addition to sample collection procedures:

Commented [AM52]: Clarity: "Cultivation facility"? I haven't seen "cultivator" used as a term.

Commented [AM53]: Clarity: Again, isn't the designee the only employee/agent trained to sample?

Commented [AM54]: Clarity: Should this be "in increments"?

	Cannabis Flower and Trim		
Batch Size Range (lbs)	Batch Size Range (kg)	Minimum Sample Amount (g)	Sample Increments Representing Total Minimum Sample Amount
0-1.00	0 - 0.453592	2.50	5
1.01-10.00	0.4581283 - 4.53592	4.00	8
10.01-20.00	4.5404596 - 9.07185	7.50	15
20.01-40.00	9.0763833 - 18.1437	11.0	22
40.01-50.00	18.148231 - 22.6796	16.50	33

~~Should~~ If a cannabis testing facility or a ~~designee of a~~ cannabis testing facility designee ~~require~~ requires ~~samples~~ a sample amount ~~exceeding~~ that exceeds the minimum sample amount for cannabis batches, as specified in the table above, ~~they~~ the testing facility or designee must use sample increments of 0.5 grams.

Commented [AM55]: Clarity: Is this specific to cannabis flowers and trim per the table above? Also, should it be "batch size range" as the table indicates?

	Cannabis Products – Concentrated Cannabis		
Batch Size Range (lbs)	Batch Size Range (kg)	Minimum Sample Amount (g)	Sample Increments Representing Total Minimum Sample Amount
0-1.00	0 - 0.453592	1.25	5
1.01-2.00	0.4581283 - 0.907185	2.00	8
2.01-5.00	0.9117207 - 2.26796	3.75	15
5.01-15.00	2.272498 - 6.80389	5.50	22
15.01-50.00	6.8084215 - 22.6796	8.25	33

~~Should~~ If a cannabis testing facility or a ~~designee of a~~ cannabis testing facility designee ~~require samples exceeding~~ requires a sample amount that exceeds the minimum sample amount for the batch size range of a cannabis product ~~batches~~ containing concentrated cannabis, as specified in the table above, ~~they~~ the testing facility or designee must use sample increments of 0.25 grams.

	Cannabis Products – Cannabis Infused Products				
Batch Size Range (Unpackaged Servings)	Minimum Sample Amount (Unpackaged Servings)	Minimum Number of UNITS for Sampling a 5-Serving Unit	Minimum Number of UNITS for Sampling a 10-Serving Unit	Minimum Number of UNITS for Sampling a 20-Serving Unit	Minimum Number of UNITS for Sampling a 100-Serving Unit
0-100	5	2	2	2	2
100-1,000	8	2	2	2	2
1,000-5,000	15	3	2	2	2
5,000-10,000	22	5	3	2	2
10,000-50,000	33	7	4	2	2
50,000-70,000	43	9	5	3	3

A serving unit is a single quantity of all pre-packaged total servings for one product package of cannabis infused product intended for sale.

The cannabis product manufacturing facility must determine the size of a ~~"~~serving~~"~~ for each cannabis infused product in accordance with ~~Chapter~~ chapter 44:90:07 ~~of this article~~, and ~~how many~~ the number of servings ~~there are~~ in the cannabis product batch. ~~In the event that~~ If the minimum required number of sample increments does not align with the anticipated final form of

Commented [AM56]: Is there a reason this is in all caps? If not, the ARSD Drafting Manual does not have a convention for using all caps just for emphasizing something.

Commented [AM57]: Style/form: Quotation marks should only be used in a definition. ARSD DM, pg. 17.

Commented [AM58]: Clarity: I only see serving size referenced in 44:90:07:04. I would recommend citing the relevant section(s) if that is the case

Commented [AM59]: Clarity: Increments are not mentioned in the table above.

the product, the cannabis testing facility or ~~designee of~~ a cannabis testing facility designee must increase sample increments to ensure products are sampled in final form.

~~Should~~ If a cannabis testing facility or ~~a designee of~~ a cannabis testing facility designee ~~require~~ requires ~~samples~~ a sample amount ~~exceeding~~ that exceeds the minimum sample amount for the batch size range of a cannabis product ~~batches~~ containing cannabis infused cannabis, as specified in the table above, ~~they~~ the testing facility or designee must use sample increments of ~~1~~ one serving.

Source:

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

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

44:90:09:07.02 Procedures to ensure representative sampling. A cannabis testing facility or a ~~designee of the~~ cannabis testing facility designee must sample in accordance with cannabis testing facility sample collection procedures and the following procedures to ensure representative sampling:

(1) Check the cannabis or cannabis product batch in its entirety for any signs or indications of non-uniformity and differences from content appearing on the batch label;

(2) Homogenize the cannabis and cannabis product batch;

(3) Confirm the cannabis or cannabis product batch size matches the information in the inventory tracking system;

Commented [AM60]: Clarity: This phrase seems redundant--a testing facility must sample in accordance with its own procedures?

Commented [AM61]: Clarity: "or"?

Commented [AM62]: Style/form: Semicolons should be after each of these subdivisions.

(4) Randomly select sample increments throughout each cannabis or cannabis product batch following sample collection procedures representing no less than the total minimum sample requirements in accordance with § 44:90:09:07;

(5) Take equal portions for each sample increment; and

(6) Record all observations and procedures used for the collection of each sample increment and maintain records pursuant to § 44:90:11:02.

Source:

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

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

44:90:09:08. Packaging of samples for testing. All samples of cannabis or cannabis products must be transferred to a testing facility in sealed and tamper-evident containers that are supplied by a testing facility or that meet criteria specified by a testing facility.

Source: 48 SDR 40, effective October 5, 2021.

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

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

44:90:09:09. Storage while awaiting test results. A cultivation facility or cannabis product manufacturing facility awaiting testing results shall:

Commented [AM63]: Clarity: This appears to be the wrong cross reference. Aren't the minimum sample sizes in 44:90:09:07.01?

(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 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: 48 SDR 40, effective October 5, 2021.

General Authority: SDCL 34-20G-72(5)(f)(1).

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

44:90:09:10. Receipt of results -- Remediation. Upon receipt of a certificate of analysis indicating that cannabis or cannabis products comply with SDCL chapter 34-20G and this article and after the cannabis testing facility updates the inventory tracking system, the cannabis cultivation facility or cannabis product manufacturing facility may transfer the cannabis or cannabis products to another medical cannabis establishment, subject to the inventory tracking requirements of this article.

Upon receipt of a certificate of analysis indicating that cannabis or cannabis products are nonusable, the cannabis or cannabis products shall remain, until remediated or destroyed in accordance with this article, in the same storage container with a new label depicting:

(1) The establishment's identification number;

(2) The batch number entered into inventory records;

(3) Name and identification number of the testing facility that will perform the tests;

(4) The sample's unique identification number;

(5) The date the samples were taken;

(6) The reason for failed analytical testing; and

(7) In bold, capital letters, no smaller than 12-point font, PRODUCT FAILED TESTING.

Source: 48 SDR 40, effective October 5, 2021.

General Authority: SDCL 34-20G-72(5)(d)(e)(f)(l).

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

44:90:09:11. Remediation of nonusable batches. A ~~cannabis~~ cultivation facility or cannabis product manufacturing facility may elect to remediate a batch of cannabis or cannabis products that failed testing, provided that:

(1) Cannabis and cannabis products that fail tests for metals or pesticides may not be remediated;

(2) Cannabis and cannabis products that fail tests for prohibited solvents may not be remediated;

(3) An establishment shall outline its processes for remediating cannabis and cannabis products in its operating procedures;

(4) An establishment shall obtain department permission before remediating a batch of cannabis or cannabis products; and

(5) Any cannabis or cannabis products must be retested and must pass all required tests after remediation.

Source: 48 SDR 40, effective October 5, 2021.

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

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

44:90:09:12. Destruction of nonusable batches. If a cultivation facility or cannabis product manufacturing facility is unable or unwilling to remediate a nonusable batch of cannabis or cannabis products, the establishment shall:

(1) Note in the inventory tracking system, or if unavailable, provide notice within one business day in writing to the department, that the establishment will destroy the cannabis or cannabis products;

(2) Follow the procedures for destroying cannabis waste in the establishment's approved operating procedures; and

(3) Ensure that destruction of the nonusable batch is captured by functioning security cameras and stored according to this article.

If a cultivation facility or cannabis product manufacturing facility fails to follow the procedures under this section, the department shall:

Commented [AM64]: Clarity: This additional paragraph seems to go beyond the catchline. Suggest adding to the catchline to reflect the department's duties for notice and recall.

~~(1) Submit~~ submit a notice to all medical cannabis dispensaries that the inventory tracking system batch number associated with the unusable batch has not passed the required tests pursuant 44:90:09:01.

~~(2) Provide~~ The department shall provide procedures for recall pursuant to § 44:90:12:02 if the unusable cannabis or cannabis product has been made available for retail sale.

Commented [AM65]: Style/form/clarity: There can't be two lists of subdivisions in one section. ARSD DM, pg. 14.

Commented [AM66]: Send? or notify? "Submit" usually refers to providing something for review or consideration.

Source: 48 SDR 40, effective October 5, 2021.

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

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

CHAPTER 44:90:11

RECORDKEEPING

Section

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.

44:90:11:12 Inconsistencies in establishment recordkeeping -- Department action.

44:90:11:13 Authorized transfers ~~--requirements~~ Requirements and procedures.

44:90:11:01. Inventory tracking ~~system -- Required use~~ -- Requirements and procedures. ~~Establishments~~ A medical cannabis establishment shall use an ~~electronic~~ inventory tracking system prescribed by the department to create all required inventory records, transfer records, testing sample records, and transaction records.

~~Establishments are required to~~ An establishment shall follow all inventory tracking system procedures, including ~~, but not limited to~~:

(1) Reconciling all on-premises and in-transit cannabis and cannabis product inventories ~~each day~~ in the inventory tracking system each day by midnight;

(2) Utilizing a standard of weights and measures that is supported by the inventory tracking system;

(3) Maintaining the security of the inventory tracking system;

(4) Monitoring all inventory tracking system notifications;

(5) Responding to all inventory tracking system notifications with appropriate responses;

Commented [AM67]: Clarity: "inventory tracking system" is already defined as an electronic system specified by the department. This language appears to be redundant.

Commented [AM68]: Clarity: This phrase is redundant as "including" already indicates that the list is not exhaustive. ARSD DM, pg. 11.

Commented [AM69]: Style/form: Each subdivision should have a semicolon.

(6) Resolving all inventory tracking system notifications that identify areas of noncompliance;

(7) Properly indicating the creation of a cannabis or cannabis product batch;

(8) Inputting the correct assigned batch number;

(9) Accurately identifying the cultivation rooms where each plant is located;

(10) Accurately identifying when inventory has departed the premises or is part of an authorized transfer with an accompanying transportation manifest.;

(11) Properly indicating all test results from a cannabis testing facility;

(12) Inputting the correct category for all cannabis and cannabis products;

(13) Providing a written explanation for any cannabis or cannabis products destruction; and

(14) Providing a written explanation for any adjustment of weights to inventory tracking system.

All establishments and ~~their~~ any inventory tracking system users and administrators shall enter data into the inventory tracking system that fully accounts for all inventory tracking activities. Any omissions or misinformation in the inventory tracking system is considered a violation of this article and SDCL chapter 34-20G.

The absence of a live~~, electronic~~ inventory tracking system prescribed by the ~~Department~~ department ~~shall~~ may not be misconstrued to excuse licensees of the requirements of Sections 44:90:11:02, 44:90:11:03, 44:90:11:04, 44:90:11:05, 44:90:11:06, 44:90:11:07, 44:90:11:08, 44:90:11:09, 44:90:11:10, 44:90:11:11, 44:90:11:12, 44:90:11:13 of this Chapter.

~~Upon Department notification~~ The department shall notify all medical cannabis establishments ~~to all licensees of a live,~~ when the ~~electronic~~ inventory tracking system ~~prescribed by the Department,~~ is live. ~~licensees shall become compliant within~~ Upon notification by the

Commented [AM70]: Clarity: This phrase does not seem to make sense.

Commented [AM71]: I'm not sure why this paragraph is highlighted. It should be removed.

Commented [AM72]: Clarity: "Licensees" is not a term used often throughout the article. Is "medical cannabis establishment" the correct term?

Commented [AM73]: Clarity: It's not necessary to list out each rule individually. It could say "the requirements of §§ 44:90:11:02 to 44:90:11:13, inclusive."

Commented [AM74]: Clarity: Suggested revisions to this paragraph to make the principal actor and requirements more clear.

department, a medical cannabis establishment shall comply with the ~~electronic~~ inventory tracking system requirements and this ~~Section~~ section within 15 days.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5).

44:90:11:02. Retention of records -- Electronic and paper -- Amended records. A medical cannabis establishment shall maintain, for a minimum of 18 months, the following records:

(1) All point of sale records, whether in electronic or paper form;

(2) Transport manifests; and

(3) Daily inventory records, transfer records, testing sample records, and transaction records.

No inventory record, transfer record, testing sample record, or transaction record may be altered after the date on which it was created. If necessary, an amended inventory record, transfer record, testing sample record, or transaction record may be created, but the original record is subject to record retention requirements.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5).

44:90:11:03. Daily inventory record. A medical cannabis establishment shall maintain and update by midnight of each day of operation, an electronic record of the establishment's inventory of cannabis and cannabis products that must:

(1) For prepackaged cannabis or cannabis products, the inventory record shall include the number of marketing layers of each item;

(2) Use the following units of measure:

(a) For seeds, seedlings, and plants, whole numbers;

(b) For cannabis flower, trim, pre-rolled cannabis cigarettes, and dry or powdered topical products, net weight in grams and ounces;

(c) For vaporizer cartridges, vaporizer pens, and concentrated cannabis, net weight in milligrams;

(d) For edible cannabis products and transdermal patches, milligrams of THC; and

(e) For ointments, creams, or lotions, net volume in fluid ounces;

(3) Reflect:

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

(b) Theft or other loss; and

(c) Data from the transfer record; and

(4) Be maintained securely and may not identify any cardholder other than by the cardholder's identification number.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5).

44:90:11:04. Daily transfer record. A medical cannabis establishment shall maintain and update by midnight of each day of operation, an electronic record of all cannabis obtained from a cardholder or another establishment, and all cannabis and cannabis products transferred to another establishment that:

(1) Use the same units of measure as the inventory record;

(2) Reflect all transport manifests; and

(3) Be maintained securely and may not identify any cardholder except by the cardholder's identification number.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5).

44:90:11:05. Daily testing sample record. A medical cannabis establishment shall maintain and update by midnight of each day of operation, an electronic testing sample record that must include:

(1) The batch identifier and quantity of each batch from which samples were drawn;

(2) The sample identifier of each sample created, its quantity, and the batch identifier associated with the sample;

(3) The tests to be performed; and

(4) Test results, including a note of whether the testing facility has indicated the batch is safe or unsafe for transfer to another establishment.

The quantity of each batch and each sample must be expressed in the same units as the inventory record.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5).

44:90:11:06. Cultivation facility inventory records -- Additional requirements. The inventory record of a cultivation facility must include a unique identifier for each immature plant and mature plant that must also be printed on a tag or label affixed to the growing container or a tag around the plant's stalk. The inventory record must be updated each time:

(1) A seedling exceeds its size limit and is considered a plant;

(2) A plant flowers for the first time;

(3) A plant is trimmed or harvested;

(4) A testing batch is created; or

(5) Cannabis is packaged for retail sale.

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

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5).

44:90:11:07. Cannabis product manufacturing facility inventory records -- Additional requirements. The inventory record of a cannabis product manufacturing facility must include the testing batch identification number of any cannabis and cannabis product obtained from a cultivation facility as follows:

(1) The inventory record must be updated each time:

(a) A quantity of concentrated cannabis is made from cannabis flower or trim;

(b) A quantity of cannabis product is made from cannabis or concentrated cannabis; or

(c) A quantity of cannabis product is packaged for retail sale~~.~~;

Commented [AM75]: Semicolon here.

(2) Any concentrate cannabis must be assigned to a testing batch, that must:

(a) Consist only of concentrated cannabis produced on a single day using the same concentration or extraction method; and

(b) Be entered into the inventory record with the identifier of any testing batch of cannabis from which it was produced~~.~~;

(3) Any cannabis product shall be assigned to a testing batch that must:

(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 of any testing batch of cannabis or concentrated cannabis from which it was produced.

The record for cannabis extracts or products packaged and labeled for transfer to a dispensary must 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: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72.

44:90:11:08. Testing facility inventory records -- Additional requirements. A testing facility shall maintain and update by midnight each day of operation, an inventory record of:

(1) All samples in its possession, with unique identifiers and quantities expressed in units specified in its operating procedures; and

(2) All other cannabis, cannabis extracts, and cannabis products acquired for training or reference purposes;

Commented [AM76]: Clarity: Isn't cannabis extract included under cannabis product, pursuant to SDCL 34-20G-1(3)?

(3) The quantity of each sample rendered unusable by testing;

(4) The quantity of each sample returned to the medical cannabis establishment;

(5) The quantity of each sample destroyed; and

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

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5).

44:90:11:09. Dispensary inventory records -- Additional requirements. The inventory record of a dispensary must include 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 all cannabis and cannabis products. The inventory record shall be updated each day of operation to reflect:

(1) Any cannabis, cannabis extracts, or cannabis products received from another establishment;

Commented [AM77]: Clarity: See previous comment.

(2) Sales to qualifying cardholders, which must include the cardholder's identification number;

(3) Returns of merchandise from cardholders, whether to be resold, returned to another establishment, or destroyed;

(4) Transfers to another establishment, including returns; and

(5) Destruction of cannabis.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5).

44:90:11:10. Daily transaction record. A dispensary shall maintain and update by midnight each day of operation, a transaction record, that must include:

(1) 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

(2) The cardholder identification number associated with each quantity. The transaction record may not contain any other identifying information relating to a cardholder.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-71, 34-20G-72(5).

44:90:11:11. Department access to and use of establishment records. ~~An~~ A medical cannabis establishment shall provide ~~to~~ the department ~~agents~~ access to all records during an inspection of an establishment or vehicle or upon request.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5), 34-20G-88.

44:90:11:12. Inconsistencies in establishment recordkeeping -- Department action. Upon the discovery of any inconsistencies in the medical cannabis establishment's record-keeping, the department shall:

(1) Make a determination of whether the inconsistencies are knowing or negligent;

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

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

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

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5), 34-20G-88.

44:90:11:13. Authorized transfers – ~~requirements~~ Requirements and procedures. ~~Establishments~~ A medical cannabis establishment may transfer cannabis and cannabis products ~~between~~ to another medical cannabis establishment~~s~~, provided the establishment follows all inventory tracking system requirements and procedures ~~in~~ of this ~~Chapter~~ chapter.

~~Establishments are required to~~ An establishment shall follow all authorized transfer procedures, including~~, but not limited to~~:

(1) Entering the correct information into the inventory tracking system identifying the transferor and the transferee; and

(2) Following all transportation and transfer requirements pursuant to §§ 44:90:04:18 through 44:90:04:24, inclusive.

Source:

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

Law Implemented: SDCL 34-20G-63, 34-20G-72(5).

Commented [AM78]: Style/form: Singular form is the preferred convention. ARSD DM, pg. 15.

Commented [AM79]: Clarity: Suggestion here with the singular form in this sentence.

CHAPTER 44:90:12

ENFORCEMENT

Section

44:90:12:07. Revocation of registry identification card for unauthorized sale. Upon a finding that a cardholder 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 pursuant to SDCL chapter 1-26. The department ~~will~~ shall notify the patient or caregiver of the revocation in writing with a supporting rationale for revocation pursuant to this section.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-36, 34-20G-72(6), 34-20G-83.

44:90:12:08. 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;

(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.

The department ~~will~~ shall notify the patient or caregiver of the revocation in writing with a supporting rationale for revocation pursuant to this section.

Source: 48 SDR 40, effective October 5, 2021.

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

Law Implemented: SDCL 34-20G-36, 34-20G-72(6), 34-20G-84.