

requirements in this part, include a notation on the marketing layer that the product does not contain THC.

9810.1103 – Product Storage

Subpart 1. **Product storage.** A license holder must develop a procedure for the storage of regulated products in a controlled environment which ensures the regulated products are free from contamination. The license holder must maintain verification records which reflect the cannabis and/or hemp workers at the facility are following the storage procedures. Storage procedures and verification records must be readily available for inspection. Product storage procedures must include the following:

- A. Product storage areas must be used only for the storage of products regulated by the office. The license holder must store regulated products in a way which ensures that there is no mixing between batch numbers or different types of products regulated by the office.
- B. A license holder must maintain and have available for inspection records which reflect when the product storage area was accessed, by whom, and which products regulated by the office were added or removed from the storage area.

Subp. 2. **Storage area specifications.** Products regulated by the office must be stored at least 6 inches above the ground of any storage area. The storage area must be clean, well ventilated, and free from condensation, sewage, dust, dirt, pests, chemicals, or other contaminants.

Subp. 3. **Secure access.** A license holder must keep their storage area locked with access restricted only to authorized personnel. Signage must be posted which indicates “Restricted Access. Authorized Personnel Only.” or the equivalent at the entrance to the storage area.

Subp. 4. **Cleaning.** When necessary, regulated products must be removed from the storage area so as to prevent contamination of the products regulated by the office while cleaning. When removed for cleaning the regulated products may be stored temporarily outside of the storage area in a manner which does not permit contamination or mixing of batch numbers or different product types. During such a time, the regulated products must be kept under close supervision.

Subp. 5. **Cannabis waste storage.** A license holder must store cannabis waste, including products which failed testing, in a secure and separate location from saleable cannabis product until such time as the cannabis waste and or failed products are disposed of or remediated. For purposes of this part, a separate, secure storage area includes a container, closet, or room which can be locked or secured.

9810.1200 – Environmental Standards and Disposal

Subpart 1. **Compliance with existing regulations.** A business operating under the authority of the office must not engage in the activity of cultivating, processing, manufacturing, selling, handling, or storing cannabis unless the business complies with the following, as applicable to the business operations:

- A. water standard requirements for disposal systems under Minnesota Rules, Chapter 7049, as administered by the Pollution Control Agency;
- B. solid waste requirements under Minnesota Rules, Chapter 7035, as administered by the Pollution Control Agency;
- C. hazardous waste requirements under Minnesota Rules, Chapter 7045, as administered by the Pollution Control Agency;
- D. energy standard requirements established in statute under the authority of the Department of Commerce or by rules adopted pursuant to those statutes or Minnesota Statutes, Chapter 342; and
- E. odor standard requirements as established in ordinance by a local unit of government or by Minnesota Statutes, section 116.064, or rules adopted pursuant to that statute;
- F. pesticide controls and requirements under Minnesota Statutes, Chapter 18B, and all rules promulgated under that chapter.

If a business is out of compliance with any of the applicable requirements in items A through E as determined by the agency authorized to enforce the requirements, the office may deny a cannabis business license application, revoke, or not renew an active cannabis business license, or take any other enforcement action under the office's authority, in accordance with Minnesota Statutes, Chapter 342.

This section does not limit the office's ability to issue a cannabis business license when the requirements of this section are not relevant to the business activities as described in the license application and when the applicant is considered otherwise fit to engage in business.

Subp. 2. **Waste and disposal.** Cannabis operators are responsible for determining the classification of all waste, including cannabis waste, of the business and for storing, securing, managing, and disposing of all cannabis waste and non-cannabis waste according to applicable local, state, and federal laws and regulations, including this chapter.

Subp. 3. **Disposal of non-hazardous cannabis waste.** Non-hazardous cannabis waste for disposal must be rendered unusable and unrecognizable prior to leaving a cannabis business location. Composting of unusable and unrecognizable non-hazardous cannabis waste is subject to part 7035.2836, as administered by the Pollution Control Agency.

Subp. 4. **Disposal of hazardous cannabis waste.** Hazardous cannabis waste must be rendered non-retrievable prior to leaving a cannabis business location. The process to achieve a non-retrievable

condition or state may be unique to the waste's chemical or physical properties. Hazardous cannabis waste is subject to Minnesota Rules, Chapter 7045, as administered by the Pollution Control Agency.

Subp. 5. **Cannabis waste exceptions.** The following materials are not considered cannabis waste and do not require treatment to render unusable and unrecognizable or non-retrievable, provided they are completely free of all cannabis flowers and leaves with any visible trichomes:

- A. root balls, soil, or growing media;
- B. stalks of cannabis plants; and
- C. leaves and branches removed from immature cannabis plants.

Subp. 6. **Reducing packaging waste.** A cannabis operator may reuse containers that are designed and constructed for reuse provided they meet the following requirements.

- A. Any prior labels or marketing is removed from the container.
- B. The container is cleaned and sanitized so as not to impart any prior cannabinoid products or harmful substances to the cannabis or cannabis products contained therein.
- C. A cannabis operator, who reuses packaging, must develop procedures for cleaning and sanitizing reusable containers. A cannabis operator must maintain records reflecting their compliance with cleaning and sanitizing reusable containers. The procedures and compliance records must be available for inspection by the office.
- D. Nothing in this section shall be construed to exempt a cannabis business operator from compliance with the packaging and labeling requirements of parts 9801-1400-1403.

Subp. 7. **Cannabis waste records.** A cannabis operator must maintain accurate and comprehensive waste-tracking records in the statewide monitoring system regarding cannabis material that accounts for, reconciles, and evidences all waste activity related to the disposal of cannabis waste and plant material.

Subp. 8. **Energy Usage Reports.** License holders who cultivate or manufacture cannabis products must annually submit to the office, on a form proscribed by the office, the amount of energy the license holder's facilities consume.

9810.1300 – Track and Trace, General Requirement

Subpart 1. **Mandatory Tracking.** Unless exempted by Minnesota Statutes, Chapter 342, or these rules, all cannabis businesses must comply with all applicable requirements under this part when purchasing, producing, selling, or possessing any products regulated by the office.

Subp. 2. **Weights and Measures.** License holders who own or operate weighing or measuring equipment for purposes of entering data in the statewide monitoring system must comply with Minnesota Rules, Chapter 7601.

9810.1301 – Track and Trace, System Administration

Subp. 1. **Designated system.** A cannabis business subject to this section must use the statewide monitoring system designated by the office, including software, tagging and labeling tools, and any other elements necessary to fulfill the inventory and tracking requirements specified in this chapter. All costs for the purchase and use of the statewide monitoring system are the sole responsibility of the licensee.

Subp. 2. **Adult use cannabis.** A cannabis business without a medical cannabis cultivation, processor, or retail endorsement under Minnesota Statutes, section 342.52 shall only record data in the adult use state-wide monitoring system.

Subp. 3. **Medical cannabis.** A cannabis business with a medical cannabis cultivation, processor, or retail endorsement under Minnesota Statutes, section 342.52 must record data for medical cannabis flower and medical cannabinoid products in the medical state-wide monitoring system.

Subp. 4. **System administrator.** A cannabis business subject to this section must designate one or more individuals as system administrators. The system administrator(s) must manage the permissions to access the statewide monitoring system of other users from the cannabis business.

Subp. 5. **Training.** A system administrator must successfully complete all required training in the use of the statewide monitoring system, as prescribed by the office. The office may require additional training for individuals to retain system administrator accounts.

Subp. 6. **Statewide monitoring system access, user accounts.** A cannabis business may designate one or more of its employees or owners as system users. A System User may access to the statewide monitoring system to conduct inventory and tracking functions. A system user must not add, terminate or manage other users, or manage settings in the statewide monitoring system. A cannabis business must ensure that each system user is properly trained and supervised by a system administrator in the proper and lawful use of the statewide monitoring system.

Subp. 7. **Administrative holds.** A cannabis business must comply with all administrative holds and any other restrictions on the sale or transfer of products regulated under Minnesota Statutes, Chapter 342, as issued through the statewide monitoring system.

Subp. 8. **Record of administrators and users.** A cannabis business must maintain a record of the name and login credentials of all system administrators and system users who have had access to the business's account in the statewide monitoring system within the past 12 months. This record must be available for inspection by the office.

Subp. 9. **System security; responsibility for use of statewide monitoring system.** A cannabis business must control access to the statewide monitoring system to prevent any unauthorized use, unlawful use, or inaccurate reporting. Each individual authorized to access the statewide monitoring system must have unique login credentials. An individual must not access the system with another individual's login

credentials. The system administrator must terminate accounts of inactive users and individuals no longer employed by the cannabis business within 24 hours.

Subp. 10. **Supplemental software allowed.** A cannabis business may use additional software that interfaces with the statewide monitoring system. All information required under this chapter must be reported in the statewide monitoring system, regardless of whether it is created or stored in another system.

9810.1302 – Track and Trace, Inventory and Tracking Requirements

Subpart 1. **Inventory management.** A cannabis business subject to this section must conduct inventory and tracking functions using the statewide monitoring system in the manner prescribed by the office.

Subp. 2. **System inventory.** A cannabis business must use the statewide monitoring system to maintain an accurate inventory of all products regulated under this section that the business has in its possession. The system inventory must include:

- A. the product category for each product in the business's possession;
- B. the quantity of each product in the business's possession, by either weight or units, as appropriate for the product category;
- C. the batch number assigned in the statewide monitoring system;
- D. for all living cannabis plants:
 - (1) the plant's current growth phase, and
 - (2) for plants over 8 inches in height or width, a unique identification number;
- E. The product's location within the facility.

Subp. 3. **Waste.** A cannabis business must report the production and disposal of all cannabis waste as described in part 9810.1200 in statewide monitoring system.

Subp. 4. **Tagging.**

- A. All cannabis plants over 8 inches in height or width, must be physically tagged with a unique identifier recorded in the statewide monitoring system.
- B. All units packaged for transfer or sale, other than for final sale or delivery to a customer, patient, or designated caregiver must be physically tagged with a unique identifier recorded in the statewide monitoring system, in the method prescribed by the office.

Subp. 5. **Additional tracking requirements.** In addition to system inventory maintenance requirements in subp. 2, a cannabis business must report the following actions and events related to products regulated under Minnesota Statutes, Chapter 342 in the statewide monitoring system:

- A. Sale, distribution, transfer, or receipt of products. Sale data must include the actual price of the product and any discount amount.
- B. Each application of a crop input to plants in the cannabis business's possession.

- C. Written explanation of any products removed from a cannabis business's inventory due to intentional or accidental destruction. The written explanation must provide justification for intentional destruction.
- D. Theft or loss of any products. Such reporting must occur within eight hours of learning of the theft or loss. The cannabis business must also notify local law enforcement of the theft or loss immediately upon learning of the theft or loss.
- E. Justification for any adjustment to the weight or quantity of any products in the cannabis business's system inventory. Reporting must be done at the time the adjustment is made.
- F. Notice of any products removed from the cannabis business's system inventory for laboratory testing. Such products must be recorded as a laboratory sample package and transferred only to a licensed testing facility.
- G. Notice of any products removed from the cannabis business's inventory for an approved demonstration purpose, such as:
 - (1) an employee sample;
 - (2) a display sample to a cannabis retailer;
 - (3) a promotional sample to a licensed cannabis business.
- H. All information required for the physical transport of products before the products leave the transferor's facility. This applies to transfers between facilities of a single license holder, and from one license holder to another.

Subp. 6. **System reconciliation.** The system inventory must be updated and made accurate at the end of each business day. Additionally, live inventory records must be accessible upon request of the office during an inspection.

- A. A cannabis business must create and make available for inspection a written procedure and schedule for verifying the accuracy of its system inventory. The procedure must be designed and implemented to ensure that the cannabis business's system inventory is accurate. The cannabis business must maintain records reflecting compliance with the procedure for verifying accuracy. Compliance records must be available for inspection by the office.
- B. A cannabis business must report the results of any laboratory testing in the statewide monitoring system within the record of the batch tested. In the case of a failed test, a cannabis business must record any remediation steps taken to address the failure, and the results of subsequent testing.

Subp. 7. **License category-specific requirements.**

- A. The reporting requirements provided in 9810.2700 apply to cannabis retailers participating in an authorized cannabis event.

- B. In addition to meeting all applicable requirements in 9810.2600, a licensed cannabis delivery service must also report receipt and delivery of products regulated under Minnesota Statutes, Chapter 342 in the statewide monitoring system.
 - (1) Product receipt from a retailer must be reported by the end of the business day of receipt or before the products are delivered to a customer, whichever is sooner.
 - (2) Product delivery to a customer, patient, or designated caregiver must be reported by the end of the business day in which the product was delivered.

Subp. 8. **Outages and manual reporting.** In the event the statewide monitoring system suffers an outage, failure, or is otherwise unavailable statewide, a cannabis business may:

- A. Manually record and report all cannabis activity for three calendar days.
- B. After three calendar days of the statewide monitoring system being unavailable all manual activity requiring reporting in the statewide monitoring system must cease except as provided in C.
- C. Reporting required for the cultivation of cannabis plants may continue with manual recording for the entirety of the time the statewide monitoring system is unavailable.
- D. Any manual reporting conducted under this subpart must be promptly entered into the statewide monitoring system when it again becomes available, no later than 12 hours following the statewide monitoring system again becoming available.
- E. This subpart does not apply to local or regional outages due to lack of electricity or internet.

9810.1400 – Packaging and Labeling Requirements

Subpart 1. **General provisions.** All businesses licensed or endorsed by the office to manufacture or produce a regulated product must comply with all applicable packaging and labeling requirements under Minnesota Statutes, Chapter 342 and this chapter. Except for label information for the sale of cannabis seeds and immature cannabis plants, all required labels must have the following:

- A. The required written words in English. In addition to the required English label, a licensee may, but is not required to, include an additional, accurate foreign language translation on the label that otherwise complies with this rule.
- B. The label affixed to the marketing layer of the package or container.
- C. Unobstructed and conspicuous placement so the label can be read by the consumer. A cannabis business may affix multiple labels to the marketing layer, provided that none of the information required by this rule is obstructed.
- D. Include the universal symbol under subpart 3 affixed to the marketing layer.

Subp. 2. **Universally applicable packaging requirements.** All packaging for regulated products under must comply with the following:

- A. Packaging may not contain or be coated with any perfluoroalkyl substance.
- B. Packaging shall not expose the product to any toxic or harmful substances.
- C. Products cannot be packaged in a container that is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.
- D. Packaging must be designed to maximize the shelf life of the product.

Subp. 3. **Universally applicable labeling requirements.** All regulated products are required to have the labels in items A-C on the marketing layer of the package or container. Each label must be marked, stamped, or otherwise imprinted directly on the package. The labels must be unobstructed and conspicuously placed so the labels can be understood by the consumer. A cannabis business or hemp business may affix multiple labels to the marketing layer, provided that none of the information required by this rule is obstructed.

- A. The universal symbol:
 - (1) must replicate the following in form and color:



- (2) must be no smaller in size than 0.5 inches by 0.5 inches and must be printed legibly and conspicuously.

B. The warning symbol:

- (1) must replicate the following in form and color:



- (2) must be no smaller in size than three-quarters (0.75) inches tall and 0.6 inches wide and must be printed legibly and conspicuously.

C. Warning statements, in no less the size 6 type:

- (1) "Keep this product out of reach of children."
- (2) "This product may be unlawful outside the state of Minnesota."

9810.1401 – Packaging and Labeling Requirements for Retail Sale

Subpart 1. **Labeling requirements applicable to immature cannabis plants and cannabis seedlings.**

Immature cannabis plants and seedlings sold to customers or patients must be labeled with the following information:

- A. name and license number of the cannabis business that cultivated the immature cannabis plants or seedlings;
- B. the net weight or net volume of the plant or seedlings in the package or container;
- C. the average or projected cannabinoid profile based on the variety; and
- D. the statement: “This plant/seedling is not required to be and has not been tested for safety compliance in accordance with Minnesota Statutes, section 342.61.

Subp. 2. **Labeling requirements applicable to dried cannabis flower products.** In addition to the labeling requirements under Minnesota Statutes, section 342.63, and parts 1400-1403, dried cannabis flower product labels must include the following:

- A. cannabinoid profile and terpene profile;
- B. strain or cultivar name, listed by scientific terms, if available;
- C. a date the product is best if used by, and;
- D. if the product includes cannabis concentrate, the information in subpart 4.

Subp. 3. **Labeling requirements applicable to ingestible cannabis products and lower-potency hemp edibles.** In addition to the labeling requirements under Minnesota Statutes, section 342.63, and parts 1400-1403, ingestible cannabis products and lower-hemp edible product labels must include the following:

- A. the cannabinoid components;
- B. all other ingredients, including excipients must be listed in a separate section of the ingredient listings in descending order of predominance by weight;
- C. the net weight or net volume of the product;
- D. serving size and number of servings per container;
- D. the THC content and CBD content per serving, expressed in milligrams per serving;
- E. the THC content and CBD content for the package in its entirety, expressed in milligrams per package;

- F. an expiration date, upon which the product is no longer fit for consumption and after which it must be destroyed;
- G. a nutritional fact panel; and
- H. major allergens declared in common name consistent with Minnesota Food Law.

Subp. 4. **Labeling requirements applicable to cannabis concentrate products.** In addition to the labeling requirements under Minnesota Statutes, section 342.63, and parts 1400-1403, cannabis concentrate labels must include the following:

- A. the name of the license holder who produced the product;
- B. date the concentrate or extract was made;
- C. the amount of cannabis concentrate per serving, as measured in grams;
- D. the amount of cannabis concentrate per package, as measured in grams;
- E. a list of ingredients;
- F. major allergens declared in common name consistent with Minnesota Food Law;
- G. an expiration date, upon which the concentrate product is no longer fit for consumption and after which it must be destroyed; and
- H. the label must contain the warning statement: "Do Not Eat."

Subp. 5. **Labeling requirements applicable to topical and transdermal.** In addition to the labeling requirements under Minnesota Statutes, section 342.63, and parts 1400-1403, topical and transdermal product labels must include the following:

- A. the manufacturer name, location, and website;
- B. the name of the independent, accredited laboratory used by the manufacturer to test the product;
- C. the net weight or net volume of the product in the package or container;
- D. the type of topical product;
- E. a potency statement describing the total THC and total CBD in milligrams in the container for topical products, and the total THC and CBD in milligrams contained in each transdermal product;
- F. the list of all ingredients in descending order of predominance by weight or volume as applicable;
- G. a recommended amount for use at any one time; and

- H. the label must contain the warning statement: “For Topical Application – Do Not Eat or Smoke.”

Subp. 6. **Labeling requirements applicable to hemp-derived consumer products.** In addition to the labeling requirements under Minnesota Statutes, section 342.63, and parts 1400-1403 of these rules hemp-derived consumer products must:

- A. comply with the requirements of subpart 2, if the product is a hemp-derived consumer product under Minnesota Statutes, section 342.01, subd. 27 (a) (1); or
- B. comply with the requirements of subpart 4, if the product is a hemp-derived consumer product under Minnesota Statutes, section 342.01, subd. 27 (a) (2).

Subp. 7. **Labeling requirements applicable to imported hemp-derived consumer products.** All hemp-derived consumer products imported into the state must be labeled in a manner that provides customers substantially similar information to the requirements applicable to hemp-derived consumer products under Minnesota Statutes, section 342.63, and these rules. In addition, imported hemp-derived consumer products must contain the following information on the label:

- A. state of origin;
- B. name and business address of the manufacturer.

9810.1402 – Packaging and Labeling for Medical Patients

Subpart 1. Universal medical label. In addition to the labeling requirements under Minnesota Statutes, section 342.63, and part 1400, all medical cannabis flower and medical cannabinoid products must be labeled with a universal label indicating the product was cultivated, manufactured, and packaged for sale to medical patients:

- A. The symbol must replicate the following in form and color:



- B. The symbol must be no smaller in size than 0.5 inches wide by 0.35 inches tall and must be printed legibly and conspicuously.

Supb. 2. Patient specific label. In addition to the information required by Minnesota Statutes, section 342.63, subd. 4, a medical cannabis combination business or cannabis retailer, microbusiness, or mezzobusiness with a medical cannabis retailer endorsement must include the following information on the patient specific label:

- A. the name and address of the medical cannabis manufacturer where the medical cannabis was manufactured;
- B. the medical cannabis's chemical composition;
- C. the recommended dosage;
- D. directions for use of the product;
- e. a notice with the statement: "This medical cannabis is for therapeutic use only. Diversion of this product is unlawful and may result in the revocation of the patient's registration."

9810.1403 – Packaging and Labeling Prohibitions

Subpart 1. **Prohibitions.** A regulated product intended for sale in Minnesota must not be labeled, packaged, or presented to the consumer in a manner that:

- A. is in violation of a federal trademark law or regulation or in a manner that would cause a reasonable consumer confusion as to whether the cannabis or cannabis product was a trademarked product;
- B. is in a manner that is specifically designed to appeal particularly to a person under 21 years of age in violation of Minnesota Statutes, section 342.62;
- C. is in a manner that obscures identifying information on the label or uses a false or deceptive label;
- D. is false, deceptive, or misleading; or
- D. represents the product as “organic” unless the cannabis plants and all ingredients used are produced, processed and certified in a manner that is consistent with the National Organic Standards established by the United States Department of Agriculture in accordance with the Organic Foods Production Act of 1990, 7 U.S.C., sections 6501 et seq.

9810.1500 – Security

Subpart 1. Responsibilities.

- A. A cannabis business must provide security at the cannabis business premises.
- B. A cannabis transporter and cannabis delivery service must provide security during transit of cannabis clones, cannabis plants, cannabis seedlings, cannabis flower, cannabis products, artificially derived cannabinoids, hemp plant parts, hemp concentrate, lower-potency hemp edibles, and hemp-derived consumer products.
- C. A cannabis event organizer must provide security while cannabis clones, cannabis seedlings, cannabis plants, adult-use cannabis flower, adult-use cannabis products, lower-potency hemp edibles, and hemp-derived consumer products are on site at a temporary cannabis event.

Subp. 2. Effective security measures.

- A. Effective security measures must consist of the following:
 - (1) alarm system;
 - (2) video surveillance;
 - (3) lighting;
 - (4) locks; and
 - (5) immediate response protocol, which must be initiated within 30 minutes from the occurrence of a security event.
- B. Nothing in this subpart shall prohibit the cannabis business from implementing additional security features that do not violate local, state, and federal laws.

Subp. 3. Testing security measures.

- A. A cannabis business must establish a protocol for testing and maintaining the required security measures which must include:
 - (1) periodic testing and inspection, occurring at least once every 90 days. The cannabis business may fulfill this requirement by contracting with outside resources capable of meeting testing and inspection needs such as a security business.
 - (2) prompt repairs to ensure the proper operation of the alarm system.
 - a. All repairs must be completed within 72 hours. If repairs cannot be completed within 72 hours and the security system is not able to operate as required by

necessary areas outlined in these rules. Any deficient or inoperable lighting must be repaired within 48 hours of detection.

Subp. 11. **Motion sensors.** Lighting can, but is not required to, include motion sensors to:

- A. light required areas that have low-light conditions;
- B. protect cultivation light-dark cycles.

Subp. 12. **Locks.** All external entrances to indoor facilities and perimeter windows on the premises must be in good condition and lockable. All perimeter entry doors, windows, gates, and fences must have commercial grade locks, including electronic locks and keypads. Interior doors, windows, gates, and fences, must have commercial grade locks, as required under Minnesota Statutes, Chapter 342.

Subp. 13. **Access to locked areas.** An individual must meet the requirements under Minnesota Statutes, section 342.24, subdivision 3 to enter a locked area, and the cannabis business must retain all required records for a period no shorter than three years.

Subp. 14. **Fencing.** Unless required under Minnesota Statutes, Chapter 342 or these rules, a cannabis business is permitted, but not required, to erect a commercial grade fence around the perimeter of the cannabis business premises. Fencing must meet the requirements of applicable local code provisions.

Subp. 15. **Outdoor cultivation.** An outdoor cultivation area must be securely surrounded by fencing and locked gates on the entire perimeter, to prevent access to the area by unauthorized persons. Fencing and all gates must be secure, at least 6 feet high and obscure, or have a cover that obscures, the fenced area from being readily viewed from outside of the fenced area. Such fencing must be commercial or security grade, not agricultural or residential grade, and designed to prevent access to the cultivation area by unauthorized persons.

Subp. 16. **Security personnel.** Unless required under Minnesota Statutes, Chapter 342, a cannabis business is permitted, but not required, to employ or contract with security guards, as defined under Minnesota Statutes, section 326.32, subdivision 13. All security guards must be 21 years of age or older and have satisfied training requirements pursuant to Minnesota Statutes, section 326.3361.

Subp. 17. **Transportation security requirements.** This section is applicable to persons and businesses engaged in the transport and/or delivery of cannabis.

- A. A cannabis business must ensure each transport and delivery vehicle is equipped with:
 - (1) a storage compartment, compliant with Minnesota Statutes, section 342.36, subdivision 3 and Minnesota Statutes, section 342.42, subdivision 5;
 - (2) a Global Positioning System (GPS) device for identifying the geographic location of the vehicle at all times when the vehicle is in operation – whether the vehicle is running or not, either permanently or temporarily affixed to the vehicle while the vehicle is in operation. The GPS data identifying the geographic location of the

vehicle must be saved and maintained for not less than 30 days. The data must be available for inspection by the office upon request;

- (3) functioning heating and air conditioning systems appropriate for maintaining correct temperatures for storage of cannabis;
- (4) carries the appropriate amount of insurance as required by the Minnesota Department of Transportation, Minnesota Department of Commerce, or applicable federal regulation.

B. A cannabis worker must:

- (1) possess their cannabis business identification card and their valid non-probationary driver's license appropriate to the type of delivery vehicle driven at all times during transport or delivery and must present them to the office or law enforcement officials upon demand;
- (2) have access to a secure form of communication, such as mobile phone, with authorized personnel at the cannabis business, at all times during the transportation or delivery of cannabis clones, cannabis plants, cannabis seedlings, cannabis flower, cannabis products, artificially derived cannabinoids, hemp plant parts, hemp concentrate, lower-potency hemp edibles, and hemp-derived consumer products;
- (3) not leave cannabis clones, cannabis plants, cannabis seedlings, cannabis flower, cannabis products, artificially derived cannabinoids, hemp plant parts, hemp concentrate, lower-potency hemp edibles, and hemp-derived consumer products in an unattended vehicle. Cannabis must not be left in a vehicle overnight or outside the operating hours of the cannabis business conducting the transportation or delivery.

9810.2000 – Cultivation

Subpart 1. **Applicability.** To cultivate cannabis for a commercial purpose a person must have a license issued under Minnesota Statutes, Chapter 342. This rule part does not apply to the cultivation of cannabis solely for personal use as allowed under Minnesota Statutes, section 342.09, or by a caregiver on behalf of a patient as allowed under Minnesota Statutes, section 342.52.

Subp. 2. **Authorized activities.** A cannabis cultivator must have approval from the office before cultivating cannabis or medical cannabis. A cannabis cultivator must submit a cultivation plan to the office as a component of the:

- A. initial license application and annual renewal;
- B. endorsement application (if applicable); and
- C. business activity change notification process.

A cannabis cultivator may only conduct the activities approved in the cannabis cultivator's submitted cultivation plan. A cannabis cultivator must notify the office of any changes to the cultivator's cultivation plan at least 10 business days before implementing the change. The change to the cultivation plan must be described on forms approved by the office submitted with all applicable fees pursuant to Minnesota Statutes, Chapter 342.

Subp. 3. **Cultivation plan and operation plan requirements.** A cultivator must indicate in its cultivation plan whether it plans to cultivate indoors or outdoors. In addition to application and business plan requirements in Minnesota Statutes, sections 342.14 and 342.25, a cultivation plan must include information describing:

- A. For indoor cultivation:
 - (1) the proposed size and layout of the facility areas that will be used exclusively for cultivation, including a diagram indicating the total canopy;
 - (2) a diagram of the proposed ventilation and air filtration systems;
 - (3) plans for providing electricity, water, and other utilities necessary for the normal operation of any cultivation activities;
 - (4) plans for wastewater disposal and solid waste disposal for any cultivation activities;
 - (5) plans for recycling any supplies or environmental inputs for cultivation, including water and packaging materials;
 - (6) a pest management protocol that incorporates integrated pest management principles as defined in Minnesota Statutes, section 17.114, subdivision 2(b), to control or prevent the introduction of pests to the cultivation site;

- (7) the vendor name, vendor contact information, and invoices for all products intended for propagation, including propagative material such as seeds and clones, fertilizers, nutrients, and pest control products, both chemical and biological;
- (8) procedures for operational record-keeping to accurately identify all crop inputs applied to plants for production and propagation purposes to be entered into the state-wide monitoring system and to be declared for laboratory testing, regulatory review, and inspection;
- (9) a description of batch numbering and plant identifier controls systems that will be used;
- (10) growing schedules that include each seeding date, planting date, or cutting and propagation cycle date as applicable;
- (11) harvesting timeline(s) and methods;
- (12) methods for drying, curing, and storage; and
- (13) plan for security as defined in part 9810.1500 and this section Subsection 8.

B. For outdoor cultivation:

- (1) the proposed size and layout of the areas that will be used exclusively for cultivation, including a diagram indicating the total amount of plant canopy that will be used for cultivation;
- (2) plans for water usage and other utilities necessary for the normal operation of any cultivation activities;
- (3) plans for wastewater disposal and solid waste disposal for any cultivation activities;
- (4) plans for recycling any supplies or environmental inputs for cultivation, including water and packaging materials;
- (5) a pest management protocol that incorporates integrated pest management principles as defined in Minnesota Statutes, section 17.114, subdivision 2(b), to control or prevent the introduction of pests to the cultivation site;
- (7) the vendor name, vendor contact information, and invoices for all products intended for propagation, including propagative material such as seeds and clones, fertilizers, nutrients, and pest control products, both chemical and biological;
- (8) procedures for operational record-keeping to accurately identify all crop inputs applied to plants for production and propagation purposes to be entered into the statewide monitoring system and to be declared for laboratory testing, regulatory review, and inspection;

- (9) a description of batch numbering and plant identifier controls systems that will be used;
- (10) growing schedules that include each seeding date, planting date, or cutting and propagation cycle date as applicable;
- (11) harvesting timeline(s) and methods;
- (12) methods for drying, curing, and storage; and
- (13) plan for security as defined in part 9810.1500 and this section Subsection 8.

C. A cultivator must:

- (1) keep its cultivation plan up to date, and
- (2) provide the office a copy of the plan on request.

Subp. 4. **Canopy.** A cultivator shall cultivate either indoors or outdoors. The total canopy is determined as follows:

- A. **Indoor facility.** For indoor grows, the canopy is measured by calculating the total square footage of each distinct cultivation area containing mature, flowering cannabis plants. Distinct cultivation areas include: trays, tables, shelves or may be demarcated by trellising, tiers, or other identifiable boundaries.
- B. **Outdoor mixed light facility.** Outdoor mixed light cultivation may occur in a greenhouse or hoophouse, and the canopy acreage is the total area of the mixed light facility containing mature, flowering cannabis plants minus any clearly demarcated walkways.
- C. **Outdoor field.** The canopy acreage for cultivation occurring completely outdoors is the total area of the field containing mature, flowering cannabis plants minus any vehicle access roads and completely fallow areas where no cultivation is occurring.

Subp. 5. **Compliance-related activities and access.**

- A. A cannabis cultivator must provide the office complete and unrestricted access to:
 - (1) all areas where cannabis plants are growing or being harvested;
 - (2) all land, buildings, and other structures used for the cultivating, handling, producing, and storage of cannabis plants;
 - (3) all locations referenced in the cannabis cultivator's license application, business plan, operation plan, and cultivation plan; and
 - (4) all records related to the production and the propagation of cannabis plants to include trimming, culling, pest scouting and control, sampling, and testing reports.

- B. A cannabis cultivator must allow the office to collect cannabis plant and cannabis flower for material laboratory analysis to establish whether the cultivator is in compliance with Minnesota Statutes, Chapter 342, and these rules. Cannabis plants and cannabis flower collected for this purpose must be provided to the office at no cost.

Subp. 6. Restrictions.

- A. A cannabis cultivator must not plant, propagate, harvest, or store cannabis plants in an area that is not identified in the cultivation plan or at a site that is not approved by the office to cultivate cannabis.
- B. The total area in square feet in which cannabis plants are cultivated must never exceed the total area for which the cannabis cultivator is approved by the office.

Subp. 7. Prohibited sales. A cannabis cultivator must not sell any propagative cannabis material resulting from cannabis cultivation activities to a buyer if the cannabis cultivator has, or should reasonably have, knowledge that the buyer would be engaging in prohibited activities under this section or applicable local, state, or federal law with the obtained cannabinoid plant product.

Subp. 8. Cannabis cultivation premises requirements.

- A. Growing, drying, processing, and storing of cannabis plants and cannabis flowers must not occur in dwellings unless the activity is specifically authorized under Minnesota Statutes, section 342.09. All activities approved by the office must occur in an area of the premises that can be accessed without passing through a dwelling space.
- B. The premises of a regulated entity under this subpart must comply with all security requirements described in part 9810.1500.
- C. All electrical equipment, including but not limited to growing lights, cultivation equipment and packaging equipment, must be evaluated and approved for the applicable use by a Nationally Recognized Testing Laboratory recognized by the Occupational Safety and Health Administration.
- D. Each production area must be configured to allow for unobstructed access to, observation of, and inventory of all plant canopy.
- E. All cultivation activities must take place in an area that ensures compliance with part 9810.1500.
- F. When sales directly to consumers on the premises where cultivation are authorized by the Office, a wall or other adequate barrier with proper security measures must be in place to separate areas of the premises designated for customers from limited access areas, including any area where samples for mandatory testing are collected, packaged, and sealed for transport to a cannabis testing facility.

Subp. 9. Sources of plants and seeds.

- A. Cannabis seeds, immature cannabis plants, cannabis mother plants, cannabis plants, and other cannabis plant sources intended for propagation must be obtained from a source authorized by the office for the sale of those products.
- B. All volunteer cannabis plants must be destroyed or disposed using a method pursuant to part 9810.1200.

Subp. 10. **Plant identification and reporting.** Each plant must be labeled with the batch number according to part 9810.1302.

Subp. 11. **Crop inputs.**

- A. All crop inputs must be:
 - (1) handled and applied in a manner that prevents contamination of cannabis plants with filth, residues, or other substances that would likely render products of the cannabis plant injurious to human health;
 - (2) in conformance with applicable sections of Minnesota Statutes, Chapters 18B, 18C, and 18D and other applicable laws;
 - (3) stored in their original containers with their original labels intact or in working containers of diluted or prepared applications labeled with information required by Minnesota Statutes, Chapters 18B, 18C, and 18D and other applicable laws; and
 - (4) documented in the statewide monitoring system according to parts 9810.1300 to 9810.1302.
- B. All crop inputs, rinsate, and containers must be diluted, applied, stored, and disposed of according to label instructions and in compliance with all other applicable laws and regulations.

Subp. 12. **Sanitary practices.** The following sanitary practices apply to all cannabis cultivation activities, including harvesting, drying, curing, and storage.

- A. Cultivation activities must be conducted in a manner to limit exposure of immature cannabis plants and cannabis plants to conditions that would likely render the products of the cannabis plants injurious to human health.
- B. All harvested cannabis plant product intended for consumption must be handled at temperatures and environmental conditions that will protect the product against physical, chemical, microbial contamination, and deterioration of product specifications or content required on labeling.
- C. Utensils and equipment, including storage containers, that come into direct contact with harvested product must be cleanable, constructed of materials that will not transfer to

harvested product, and maintained in good condition that prevents contamination of harvested product.

- D. Packaging materials that come into direct contact with harvested product must be stored and handled in a manner to prevent contamination from the environment, and:
 - (1) cleaned between uses if designed for cleaning and multiple uses, or
 - (2) discarded after single use.

Subp. 13. Recordkeeping.

- A. Records of cultivation activities must be kept and maintained in the state-wide monitoring system according to parts 9810.1300 to 9810.1302. At a minimum, records of cultivation activities must document the following:
 - (1) initiation of cultivation for each batch;
 - (2) application of crop inputs to the growing medium, plants, or plant material used in production;
 - (3) maintenance of plants that involves culling of plant parts or plant disposal; and
 - (4) harvesting of each plant batch.
- B. Cultivation records must include at minimum the following information for each cultivation activity being recorded:
 - (1) the date the activity was completed;
 - (2) the name of the worker completing the activity, or the name for the responsible worker when more than one worker;
 - (3) the name and description of the activity that was completed;
 - (4) batch number; and
 - (5) the section where the action was completed;
- C. For initiation:
 - (1) the source of immature cannabis plants or seeds; and
 - (2) the volume in count.
- D. For crop inputs:
 - (1) the weight and concentration of the crop input that was applied;
 - (2) a copy of the label of the crop input applied; and

- (3) the vendor or other origin of the crop input.

Subp. 14. **Medical and adult use cultivation.** A licensee that is endorsed or authorized to cultivate both medical and adult use cannabis shall only be allowed to cultivate medical and adult use cannabis on the same premises, if the licensee is in compliance with this subpart.

A. A cultivation facility may cultivate both medical cannabis and adult use cannabis only if:

- (1) the facility has received the office's approval of a facility plan to cultivate both; and
- (2) the facility has a valid medical cannabis endorsement issued under Minnesota Statutes, section 342.51 or is licensed under Minnesota Statutes, section 342.515.

B. If a cultivation facility is cultivating both medical cannabis and adult use cannabis, the cultivation facility must:

- (1) cultivate medical cannabis in an area separated from the area used to cultivate adult use cannabis;
- (2) track all medical cannabis separately from adult use cannabis;
- (3) store all medical cannabis separately from adult use cannabis;
- (4) ensure that medical cannabis is never cultivated simultaneously with adult use cannabis on the same piece of equipment; and
- (5) keep a log for each piece of equipment used to cultivate both medical cannabis and adult use cannabis. The log must be made available to the Office and contain the following information:
 - a. the name of the cannabis worker who operated the equipment;
 - b. the tracking information for the cannabis or cannabis concentrate that was processed using the equipment;
 - c. the exact date, time and duration the equipment was used; and
 - d. the tracking information for the resulting cannabis concentrate or cannabis product.

9810.2100 – Approved Cannabis and Hemp Product Categories

Subpart 1. **Dried cannabis flower products.** Dried cannabis flower products are made up of cannabis flower and may contain cannabis concentrates. Such products include:

- A. dried raw cannabis flower;
- B. bud;
- C. trim;
- D. shake;
- E. pre-rolls; and
- F. infused pre-rolls.

Subpart 2. **Ingestible cannabis products.** The following are approved Ingestible Cannabis products:

- A. edible products; and
- B. beverage products.

Subp. 3. **Cannabis concentrates.** Cannabis concentrates means a product derived from cannabis that has undergone a process to concentrate one or more active cannabinoids, and include:

- A. hash;
- B. hash oils;
- C. live resin;
- D. kief;
- E. resin;
- F. shatter;
- G. tinctures;
- H. total extract;
- I. wax; and
- J. any other product produced by extracting cannabinoids from the plant using solvents, carbon dioxide, heat, screens, presses or steam distillation.

Subp. 4. **Topical and transdermal cannabis and hemp products.** Topical and transdermal cannabis and hemp products include:

- A. balms;
- B. lotions;
- C. ointments;
- D. rubbing alcohol solutions; and
- E. patches.

Subp. 5. **Lower-potency hemp edibles.** Lower-potency hemp edibles are defined in Minnesota Statutes, section 342.01, subd. 50.

Subp. 6. **Hemp-derived consumer products.** The following are approved Hemp-derived consumer products:

- A. dried raw hemp flower;
- B. hemp-derived oils intended to be consumed by combustion or vaporization of the product and inhalation of smoke, aerosol, or vapor from the product.

9810.2101 – Production and Potency Limits

Subpart 1. **Cannabis manufacturing production limits.** On an annual basis, the following license holders may not use more than the following volume of cannabis or its dry-weight equivalent of raw concentrates to manufacture regulated products:

- A. Cannabis Manufacturing License: 20,000 pounds.
- B. Mezzobusiness license: 10,000 pounds.
- C. Microbusiness license: 3,000 pounds.
- D. Medical combination business: 50,000 pounds, of which at least two-thirds must be used for the medical market.

Subp. 2. **Potency limits.** Unless otherwise stated in law, no product shall exceed these potency limitations:

- A. Cannabis concentrates marketed for sale in the adult-use market shall not exceed 70% THC potency.
- B. Topical and transdermal cannabis and hemp products shall not contain more than 1500 mgs of THC.
- C. Lower-potency hemp edibles and hemp-derived consumer products shall not exceed 0.3% THC potency.
- D. The weight of cannabis concentrate added to a smokeable cannabis product may not exceed 30% of the weight of cannabis flower in the smokeable cannabis product.
- E. The weight of cannabis concentrate added to a smokeable cannabis product may not exceed 30% of the weight of cannabis flower in the smokeable cannabis product.

9810.2102 – Manufacturing Facilities

Subp. 1. **Authorized activities.** A cannabis operator must have approval from the office before manufacturing products regulated under Minnesota Statutes, Chapter 342. For approval a cannabis operator must submit a manufacturing plan to the office as a component of the:

- A. initial license application and annual renewal;
- B. endorsement application, when applicable; and
- C. business activity change notification process.

A cannabis operator may only conduct the manufacturing activities approved from the submitted manufacturing plan. A cannabis operator must notify the office of any changes to the manufacturing plan at least 10 business days before implementing the change. The change to the manufacturing plan must be described on forms approved by the office and all applicable fees paid pursuant to Minnesota Statutes, Chapter 342. If the change to the manufacturing plan includes relocation of the licensed manufacturing facility, additional fees pursuant to Minnesota Statutes, section 342.12, must be paid at the time the change to the manufacturing plan is submitted to the office.

Subp. 2. **Manufacturing plan requirements.**

- A. In addition to application and business plan requirements in Minnesota Statutes, sections 342.14 and 342.25, a manufacturing plan must include information describing:
 - (1) planned regulated product types and planned volumes of production;
 - (2) the proposed size and layout of the facility areas that will be used exclusively for manufacturing, including a diagram indicating the equipment placements;
 - (3) a diagram of the proposed ventilation and air filtration systems;
 - (4) plans for providing electricity, water, and other utilities necessary for the normal operation of any manufacturing activities;
 - (5) plans for wastewater disposal and solid waste disposal for any manufacturing activities;
 - (6) plans for recycling any supplies, inputs, ingredients, or work-in-progress for manufacturing, including water and packaging materials;
 - (7) a pest management protocol to control or prevent the introduction of pests to the manufacturing site;
 - (8) the sources of all ingredients and inputs intended for use the manufacturing process;

- (9) all processing steps to include potential product related biological, chemical, and physical hazards applicable to the step, and planned actions to control the identified hazards;
- (10) standard operating procedures for sanitary handling of ingredients, in-process product, finished products, and packaging materials;
- (11) standard operating procedures for the control of personal use regulated product that is processed within the facility to ensure the product:
 - a. is not a source of contamination to the non-personal use product in the facility;
 - b. is handled to the same level of safety as non-personal use product; and
 - c. all personal use product is returned to the same individual requesting processing.
- (12) a description of batch numbering and plant identifier controls systems that will be used;
- (13) methods for securing inputs and ingredients regulated under Minnesota Statutes, Chapter 342 and in process products after the addition of those inputs and ingredients; and
- (14) procedures for operational record-keeping of each batch to accurately identify all inputs, processes, and waste necessary to be entered into the state-wide monitoring system and to be declared for laboratory testing, regulatory review, and inspection.

B. An operator must:

- (1) keep its manufacturing plan accurate and up to date to reflect current practices; and
- (2) provide the office a copy of the plan on request.

Subp. 3. Compliance-related activities and access.

A. A cannabis operator must provide the office complete and unrestricted access to:

- (1) all areas where products regulated under Minnesota Statutes, Chapter 342 are received, handled, processed, stored, and shipped;
- (2) all land, buildings, and other structures used for the manufacturing and storage of products regulated under Minnesota Statutes, Chapter 342;
- (3) all technical specifications for products, processes, and equipment used in the production of products regulated under Minnesota Statutes, Chapter 342; and

- (4) all records related to the production of products regulated under Minnesota Statutes, Chapter 342 to include all associated analysis and testing requests and reports.
- B. A cannabis operator must allow the office to collect inputs, ingredients, in-process product, packaging, and finished product for laboratory analysis to establish whether the operator is in compliance with Minnesota Statutes, Chapter 342 and these rules. Items collected for this purpose must be provided to the office at no cost.

Subp. 4. Restrictions.

- A. A cannabis operator must not conduct manufacturing activities in an area that is not identified in the manufacturing plan or at a site that is not approved by the office to manufacture regulated product.
- B. A cannabis operator must not produce in excess of:
 - (1) the limit established in part 9810.2201; and
 - (2) the amount for which the cannabis operator is approved by the office.
- C. Only products and product types approved by the office can be manufactured. All products must comply with the requirements of Minnesota Statutes, section 342.06.
- D. When personal use product is handled for the purpose of manufacturing, all product must be returned to the individual requesting processing or be disposed according to part 9810.1200.

Subp. 5. Prohibited sales. A cannabis operator must not sell any cannabinoid product resulting from cannabis manufacturing activities to a buyer if the cannabis operator has, or should reasonably have, knowledge that the buyer would be engaging in prohibited activities under this section or applicable local, state, or federal law with the obtained cannabinoid plant product.

Subp. 6. Cannabis manufacturing premises requirements. Manufacturing operations must take place in a facility which meets the applicable requirements of Minnesota Statute, section 342.26. Additionally, the premises must:

- A. have adequate physical space for all manufacturing activities including storage to occur in a fully enclosed and secured indoor facility as described in part 9810.1104, that prevents entry by unauthorized persons;
- B. be supplied with electrical service, water service, sewer service or treatment, and other utilities necessary for the operations approved by the office.
- C. have ventilation and air-handling systems with temperature and humidity controls adequate for safe processing and sanitary operations;

- D. be supplied with lighting fixtures adequate to perform manufacturing activities and sanitation functions safely and sanitarily;
- E. have floors, walls, and ceilings in the manufacturing area that are constructed with surfaces that can be easily cleaned and maintained in good repair to inhibit microbial growth;
- F. have hand washing facilities located in all manufacturing areas where handling of unpackaged product occurs;
- G. have each production area configured to allow for unobstructed access to, observation of, and inventory of all ingredients, in-product product, and finished products;
- H. have, when sales directly to consumers on the premises where manufacturing are authorized by the office, a fence or other adequate security measures must be in place to separate areas of the premises designated for customers from limited access areas, including any area where samples for mandatory testing are collected, packaged, and sealed for transport to a cannabis testing facility.
- I. Dried cannabis flower manufacturing facilities have additional requirements found in part 9810.2203.
- J. Ingestible and lower-potency hemp edible manufacturing facilities have additional requirements found in part 9810.224.
- K. Concentration facilities have additional requirements found in part 9810.2205.

Subp. 8. Sources of ingredient from cannabis and hemp.

- A. All products regulated by the office being used in the manufacturing process must be purchased, acquired, and received from a license holder permitted to distribute such products regulated by the office, or by a Minnesota tribally licensed cannabis business.
- B. Hemp derived ingredients sourcing:
 - (1) from compliant hemp grown under the authority of a federally compliant hemp program; or
 - (2) must be purchased, acquired, and received from a license holder permitted to distribute such products regulated by the office, or by a Minnesota tribally licensed cannabis business.

Subp. 9. Batch identification and reporting. Each plant must be labeled with the batch number according to part 9810.1302.

Subp. 10. Manufacturing inputs and ingredients. All products other than cannabis derived ingredients and hemp derived ingredients must be:

- A. Safe for the intended purpose and use in the manufacturing process. Any solvent used in manufacturing must be safe for human consumption and approved for use in foods by the FDA.
- B. Handled and used in a manner that prevents contamination with filth, residues, or other substances that would likely render products of the cannabis plant injurious to human health:
 - (1) in conformance with applicable sections of Minnesota Statutes, Chapters 18B, 18C, and 18D and other applicable laws; and
 - (2) stored in their original containers with their original labels intact or in working containers of diluted or prepared applications labeled with information required by Minnesota Statutes, Chapters 18B, 18C, and 18D and other applicable laws.
- B. All manufacturing inputs, ingredient, and containers must be used, stored, and disposed of according to label instructions and in compliance with all other applicable laws and regulations.

Subp. 11. **Sanitary practices.** Sanitary practices must be followed during all manufacturing activities including receiving, storage, processing, handling, packaging, and labeling. Sanitary practices at minimum must:

- A. Ensure all individuals experiencing illness or communicable disease does not perform any tasks that might contaminate products regulated by the office.
- B. Ensure handwashing facilities in manufacturing areas are supplied with:
 - (1) running water at a temperature suitable for use by workers;
 - (2) effective hand cleaning and sanitizing solutions; and
 - (3) sanitary drying functions such as electronic drying devices, single use towels, or sanitary towel service.
- C. Ensure all workers in direct contact with products regulated by the office use hygienic practices, including but not limited to maintaining cleanliness of outer garments and washing hands thoroughly in a hand-washing area before starting work and at any other time when the hands may have become soiled or contaminated.
- D. Control environmental conditions and handling practices effectively to protect the product against physical, chemical, and microbial contamination. This includes storing in a manner to prevent the growth of those microorganisms when product may support the rapid growth of undesirable microorganisms.
- E. Controls environmental conditions to prevent the deterioration of product specifications or content required on labeling.

- F. Provide tools, utensils, and equipment, including storage containers, that comes into direct contact with ingredients, in process product, and finished product that are cleanable in design, constructed of materials that will not transfer to ingredients or finished product.
- G. Cleaning of all product contact surfaces to include utensils and equipment used in the production of products are maintained in a condition that prevents contamination of harvested product.
- H. Packaging materials that come into direct contact with ingredients, in-process product, and finished product must be:
 - (1) safe for use with the intended product; and
 - (2) stored and handled in a manner to prevent contamination of materials from the environment; and
 - (3) cleaned between uses if designed for cleaning and multiple uses, or discarded after single use.
- I. Effective mechanisms to prevent pest is in place to include:
 - (1) screening or other protection against the entry of pests is provided;
 - (2) rubbish is disposed of to minimize the development of odor and the potential for the waste becoming an attractant, harborage, or breeding place for pests.
- J. Identifying and storing toxic cleaning compounds, sanitizing agents, and other potentially harmful chemicals in a separate location away from products regulated by the office and in accordance with applicable local, state, and federal workplace safety requirements.

Subp. 12. Recordkeeping.

- A. Records of each batch of manufactured product must be kept and when applicable also maintained in the state-wide monitoring system according to parts 9810.1400 to 9810.1402. At a minimum, records of manufacturing activities must document the following:
- B. Manufacturing records must include at minimum the following information for each manufacturing activity being recorded:
 - (1) the date the activity was completed;
 - (2) the name of the worker completing the activity, or the name for the responsible worker when more than one worker;
 - (3) the process step or description of the activity that was completed;
 - (4) relevant process control measurements; and

- (5) batch number.

Subp. 13. **Medical product and non-medical product manufacturing.** A licensee that is endorsed or authorized to manufacture both medical cannabinoid and cannabis products be allowed to manufacture medical and adult use cannabis on the same premises, if the licensee is in compliance with this subpart.

- A. A manufacturing facility may manufacture both medical cannabis and adult use cannabis products only if:
 - (1) the facility has received the office’s approval of a manufacturing plan to manufacture both; and
 - (2) the facility has a valid endorsement to process medical cannabinoid products issued under Minnesota Statutes, section 342.51.
- B. If a cannabis operator is manufacturing both medical cannabis and adult use cannabis, the manufacturing facility must:
 - (1) track all medical cannabis separately from adult use cannabis;
 - (2) store all medical cannabis separately from adult use cannabis;
 - (3) ensure that medical cannabis is never manufactured simultaneously or contemporaneously with non-medical cannabis product on the same piece of equipment; and
 - (4) maintain records production records for each piece of equipment used to cultivate both medical cannabis and adult use cannabis. The log must be made available to the office and contain the following information:
 - a. the name of the individual who operated the equipment;
 - b. the tracking information for the cannabis or cannabis concentrate that was processed using the equipment;
 - c. the exact date, time and duration the equipment was used; and
 - d. the tracking information for the resulting products.

9810.2203 – Dried Cannabis Flower Product Manufacturing Requirements

Subdivision 1. **Authorized Activity.** A manufacturer may manufacture dried cannabis flower products into saleable cannabis products.

Subd. 2. **Labeling.** A manufacturer may sell multiple uniform dried cannabis flower products to another cannabis business under a single label so long as the label reflects the number of units or weight of the product being sold.

Subd. 3. **Infused smokeable products.** A manufacturer with an endorsement to produce cannabis or hemp concentrate may manufacture dried cannabis flower products combined with cannabis concentrate, but an infused dry cannabis flower product may not be infused with anything other than cannabis derived products.

9810.2204 – Ingestible Cannabis Product Manufacturing Requirements

Subpart. 1 **Authorized activity.** A manufacturer may only produce ingestible cannabis products or lower-potency hemp edibles if they have the appropriate licenses and/or endorsements provided in Minnesota Statute, Chapter 342.

Sub. 2. **Minnesota food laws.** ingestible cannabis products and lower-potency hemp derived edibles must be manufactured according to the applicable provisions of Minnesota Food Law, including applicable sections of the Code of Federal Regulations which are adopted by reference in Minnesota Statutes, section 31.101, with the exception that the product is not adulterated solely due to the presence of cannabis or hemp ingredients.

Subp. 3. **Homogenous product.** A ingestible cannabis products or lower-potency hemp edible manufacturer must use production methods which result in a finished product batch with consistent servings and consistent packages, and prepared in a manner to ensure each individual serving has a consistent amount of cannabinoid ingredients, pursuant part 9810.3100. A manufacture must at minimum:

- (1) develop stable product formulations that consider and address specific ingredients and the nature of the finished product;
- (2) establish written procedures for the preparation of edible cannabis products or lower-potency hemp edibles specific to the manufacturing site;
- (3) maintain batch records that demonstrate adherence to the formulation and the written procedures.

9810.2205 – Cannabis Concentrate Manufacturing Requirements

Subpart. 1. **Facilities:** Extraction and concentration systems must be designed to effectively and consistently function, operate safely, and provide sanitary production conditions as certified by an industrial hygienist or professional engineer qualified to conduct the certification through education, experience, or professional credentialing.

- A. Qualifications of certifying individual must be maintained in writing as part of the record of certification.
- B. Certification must include an assessment of all of the following as applicable to the system:
 - (1) all electrical, gas, fire suppression, and exhaust systems; and
 - (2) the plan for safe storage and disposal of hazardous substances, including but not limited to any volatile chemicals.
- C. Certifications must be completed, documented, and approved by the office prior to the production of product intended for sale or distribution.

Subp. 2. **Inactive ingredients.** Only non-cannabis derived inactive Ingredients listed in the Federal Food and Drug Administration Inactive Ingredient Database may be used in the manufacture of cannabis or hemp-derived concentrate intended for use through a vaporizer delivery device or pressurized metered dose inhaler. Nothing in this subpart prohibits a manufacturer from using cannabis-derived ingredients.

Subp. 3. **Prohibited ingredients.** A manufacturer shall not use the following ingredients when manufacturing cannabis concentrate:

- A. Polyethylene glycol (PEG);
- B. Vitamin E Acetate; or
- C. Medium Chain Triglycerides (MCT Oil).

9810.2300 – Transportation

Subpart 1. **Applicability.** A cannabis business holding a valid transporter license must establish a standard operating procedure to ensure compliance with Minnesota Statutes, Chapters 221, 342, and this rule part. A cannabis business holding a valid transportation license must comply with all commercial vehicle requirements imposed by the Minnesota Department of Public Safety, the Minnesota Department of Commerce, and the Minnesota Department of Revenue.

Subp. 2. **Covered products.** A cannabis transporter must comply with this part when regulated products or any other products designated by the office.

Subp. 3. **Shipping manifest.** Before accepting products covered under this part from a license holder, a cannabis transporter must obtain a shipping manifest. The shipping manifest must be produced using the statewide monitoring system and include the following information:

- A. the name, phone number, address, and license number of the cannabis transporter;
- B. the name, phone number, address, and license number of the originating entity;
- C. the name, phone number, address, and license number of the destination entity;
- D. the type and quantity of all covered products to be transported;
- E. the name of each employee or contractor of the cannabis transporter who will participate in the transportation of the covered products;
- F. the make, model, year, and license plate number of each cannabis delivery vehicle;
- G. the planned route;
- H. the date and time of estimated departure and arrival.

A copy of the shipping manifest must accompany the products covered under this part until they are delivered. The shipping manifest must be available for inspection at any point during transportation. Upon inspection by an agent of the office, a cannabis transporter may provide the shipping manifest in digital or physical form.

Subp. 4. **Motor vehicle.** Motor vehicles used for cannabis transport regulated under this part must be properly registered in the state of Minnesota.

Subp. 5. **GPS tracking.** A cannabis transportation vehicle must be equipped with an active global positioning system or other a similar satellite-based tracking system.

Subp. 6. **Product secured during transportation.** During transportation, all products covered under this part must be maintained in either a locked compartment of the cannabis delivery vehicle or a locked container inside the cannabis delivery vehicle.

- A. The entire cargo bay, cargo area, or trunk of a cannabis transportation vehicle may be used for holding of products covered under this part if:
 - (1) it is protected by a locking mechanism with a lock or keypad separate from vehicle door locks;
 - (2) it is inaccessible from the driver and passenger areas of the cannabis transportation vehicle and;
 - (3) products stored in the compartment are not visible from outside the cannabis transportation vehicle.
- B. A container that is not integral to the cannabis delivery vehicle may be used for holding products covered under this part if:
 - (1) the container is locked;
 - (2) the container is secured to prevent removal from the vehicle; and
 - (3) products stored in the container are not visible from outside the cannabis transportation vehicle.

Subp. 7. **Identifying logos and business names.** A cannabis transportation business's vehicles must not contain any images prohibited under Minnesota Statute, section 342.36, and must comply with Minnesota Statutes, section 221.031 subd. 6 and 49 CFR 390.21.

Subp. 8. **Transportation routes.**

- A. A cannabis transporter must make reasonable efforts to ensure that driving routes and delivery times are randomized. At a minimum randomizing routes requires that the same individual does not on a reoccurring scheduled basis:
 - (1) deliver to the same business;
 - (2) on the same day of the week; and
 - (3) at the same time of day.
- B. A cannabis transporter must not deviate unnecessarily from a planned route or schedule. Necessary stops, changes to a route, or changes to departure or delivery times must be noted on the shipping manifest associated with the delivery and recorded in the statewide monitoring system.

Subp. 9. **Vehicle occupants.** A cannabis transportation vehicle that is transporting regulated products must be staffed by at least two individuals and at least one individual must remain with the vehicle at all times. All occupants of a cannabis transportation vehicle must be cannabis workers employed by or contract with the cannabis transporter:

- A. who are at least 21 years of age;
- B. carry a valid driver’s license with proper endorsements while operating a cannabis transportation vehicle.

Subp. 10. **Inspection.** All vehicles used by a cannabis business for transportation must comply with all applicable laws, statutes, regulations, and rules for commercial vehicle inspection.

9810.2400 – Wholesale

Subpart 1. **Authorized activities.** A licensed cannabis wholesaler may purchase lower-potency hemp edibles from a lower-potency hemp edible manufacturer.

Subp. 2. **Imported hemp-derived consumer products.** A cannabis wholesaler that imports a hemp-derived consumer product from outside the state of Minnesota must record the following information in the statewide monitoring system before the imported hemp-derived consumer product may be distributed, sold, or transferred:

- A. manufacturer name, address, and contact information;
- B. finished product testing results showing contaminant levels in the following categories do not exceed the acceptance criteria established by the office:
 - (1) foreign material;
 - (2) heavy metals;
 - (3) microbiological contaminants;
 - (4) mycotoxins;
 - (5) pesticide residue; and
 - (6) residual solvents.
- C. The finished product must be tested for all criteria unless the manufacturer demonstrates that the cannabis or hemp derived ingredient used was tested and shown to meet criteria, and the production process.

9810.2500 – General Retail

Subpart 1. **Applicability.** This part applies to retail sales of all regulated products.

Subp. 2. **Sanitary and clean conditions.** Retail areas must be kept in a clean and sanitary condition and comply with the following:

- A. Retail areas must include proper ventilation and filtration for odor control, pursuant to state and local requirements.
- B. Handling of edibles and beverages must be performed pursuant Minnesota Rules, Chapter 4626, and any other relevant local, state, and federal law.
- C. Retailers must develop, document, implement, and maintain procedures detailing handling of cannabis product, flower, plants, and lower-potency hemp products.
 - (1) Retailers must maintain record demonstrating that the handling procedures are being complied with.
 - (2) Such records must be available for inspection by the office.

Subp. 3. **Fraudulent identification.** Retailers must develop, document, implement, and maintain procedures for the detention of fraudulent identification documents. Retailers must maintain records demonstrating that the detention of fraudulent identification documents are being complied with. Such records must be available for inspection by the office.

Subp. 4. **Signage.**

- A. Cannabis businesses and hemp businesses must post all required signage as required by the Minnesota Department of Labor and Industry.
- B. Cannabis businesses and hemp businesses may include signage that states hours of operation.

9810.2501 – Adult -Use Cannabis Retail

Subpart 1. **Specified retail sales area.** Retailers must establish a specified area for conducting retail sales, that is open to individuals who are 21 years or older or registered in the medical cannabis patient registry.

- A. The retail area must include a point-of-sale system.
- B. Each point of ingress must have conspicuous signage with the following statement: “No persons under 21 allowed.”

Subp. 2. **Age verification.**

- A. Retailers must confirm that individuals within the retail area are 21 years of age or enrolled in the medical cannabis patient registry – or their registered caregivers.
- B. Retailers must confirm an individual’s age or enrollment in the medical cannabis patient registry at the time of sale of any item regulated by the office.
- C. Retailers must confirm individuals age using one of the documents provided for in Minnesota Statutes, section 342.27, subdivision 4(b).

Subp. 3. **Restricted access areas.** It is the sole responsibility of the license holder to control access to restricted areas. The Retailer must ensure that only authorized personnel or members of the office have access to restricted areas.

- A. Retailers must maintain an entry log detailing the entry of an individual to restricted access areas, which must include:
 - (1) name;
 - (2) time of entry;
 - (3) time of exit; and
 - (4) date.
- B. Retailers must mark all entries to restricted access areas with conspicuous signage that must state: "WARNING: RESTRICTED AREA, AUTHORIZED PERSONEL ONLY."

Subp. 4. **Display samples.**

- A. Displays may include up to one sample of each product offered.
- B. Retailers must employ methods to prevent theft or access to the display sample.
- C. Display samples must be treated as contaminated product.

- D. Display samples must be destroyed no later than 90 days after being designated as a display sample.
- E. Samples that are offered to smell must have a preventative measure to prevent the sample from being accessed by a customer.

Subp. 5. **Pre-orders.** A cannabis business with a retail endorsement store may accept orders and payment for regulated products over the internet or through a mobile app or telephone.

- A. Cannabis retailers who use online sales must:
 - (1) require all submitted orders to include the customer's name, address, phone number, email address, and date of birth;
 - (2) prior to providing the order to the customer either in store or via a delivery, verify:
 - a. the customer's physical identification matches the name and date of birth the customer provided at the time of the order; and
 - b. that the customer is twenty-one years of age or older, in accordance with subpart 2.
- B. A retail marijuana store may accept payment using any legal method of payment, gift card pre-payments, or pre-payment accounts established with a retail marijuana store except that any payment with an electronic benefits transfer services card is not permitted.
- C. A retailer must collect only the information necessary to complete the transaction, and such information shall be used only for the purpose of completing the transaction and must establish an SOP for data security and privacy that applies to the cannabis retailer and third-party the cannabis retailer contracts with for the purposes of offering online sales.

9810.2502 – Medical Cannabis Retail

Subpart 1. **Applicability.** This part applies to retail sales of all medical cannabis flower, medical cannabinoid products, and other products regulated under Minnesota Statutes, Chapter 342, sold by a medical cannabis retailer.

Subp. 2. **Identity verification.** Prior to distributing medical cannabis flower or medical cannabinoid products, a medical cannabis retailer must verify the identity of the recipient and, if applicable, the associated patient's enrollment in the registry. A patient or caregiver, must present the following to the medical cannabis retailer for verification:

- A. valid government-issued photo identification; and
- B. the patient's medical cannabis program verification document, registry number, or other proof the patient is actively enrolled in the registry.

Subp. 3. **Patient self-evaluation.** During the first year of enrollment, patients must complete a self-evaluation upon first purchase of medical cannabis flower or medical cannabinoid products and every three months thereafter. A medical cannabis retailer must only distribute medical cannabis flower or medical cannabinoid products to patients with an up-to-date self-evaluation in the registry, as applicable. Patients may complete their required self-evaluation on site prior to distribution.

Subp. 4. **Patient self-evaluation; verification.** Prior to distribution of medical cannabis, a medical cannabis retailer must verify a patient self-evaluation is completed as required under subpart 3. If a self-evaluation is required and the patient has not completed it, the medical cannabis retailer must assist the patient in completing the self-evaluation.

Subp. 5. **Patient consultation.** A licensed pharmacist or certified medical cannabis consultant must be available to provide consultation to the patient or caregiver to determine the proper medical cannabis flower or medical cannabinoid product, recommended dosage, and paraphernalia for the patient if required under Minnesota Statutes, section 342.51, subdivision 3(a). A patient consultation must include:

- A. review of patient information in the registry;
- B. review of the range of chemical compositions of medical cannabis flower or medical cannabinoid products intended for distribution;
- C. an assessment of the perceived effectiveness of the medical cannabis flower or medical cannabinoid product intended for purchase at treating the condition or symptoms of the condition; and
- D. as applicable, any relevant information on the use of medical cannabis paraphernalia.

Subp. 6. **Patient-specific labeling.** Prior to distributing medical cannabis flower and medical cannabinoid products to the patient or caregiver, a pharmacist or certified medical cannabis consultant must apply a

patient-specific label to the medical cannabis flower and medical cannabinoid products in accordance with part 9810.1403.

9810.2503 – Lower-Potency Hemp Edibles Retail

Subpart 1. **General requirements.** This part applies to the retail sale of lower-potency hemp edibles, by a lower-potency hemp edible retailer. Retailers regulated by this section must:

- A. ensure that all products sold comply to the requirements for packaging and labelling under parts 9810.1400 to 9810.1403;
- B. all display of lower-potency hemp edibles must comply with Minnesota Statutes, section 342.46, subdivision 4 and Minnesota Rules, part 9810.2501, subpart 4, except that lower-potency edibles that are intended for consumption as a beverage may be stored in a refrigerator or similar cooling unit; and
- C. must verify the age of the customer, as prescribed in Minnesota Statutes, section 342.27, subdivision 4, prior to any sale.
- D. Beverages may be sold in multi-pack units such as cases as long as the outer packaging states clearly the number of individual units inside, the potency and number of servings per unit, and contains the required universally applicable labeling requirements and universal symbol, as set forth in part 9810.1400 Subp. 2 and 3.

Subp. 3. **Inspections.** All lower-potency hemp edible retailers must comply with regulatory inspections and requests for records by the office.

Subp. 4. **On-site consumption.** On-site consumption of lower-potency hemp edibles may be permitted by a licensed retailer with the proper on-site consumption endorsement, under the following conditions:

- B. Testing must be done by batch to verify compliance with acceptable contaminant levels as established by the Office for beverages prepared off-site in bulk and dispensed individually, such as from kegs.
- C. Testing for homogeneity and shelf-stability but be done by the manufacturer of the bulk beverages to ensure beverage dispensed have consistent potency over time.
- D. Lower-potency hemp beverages stored in bulk and dispensed individually, such as from kegs, must:
 - (1) be dispensed only in a single serving;
 - (2) with no more than 5 mg of THC per serving; and
 - (3) and the serving size may not be less than 8 fluid ounces.
- E. Lower-potency hemp beverages may be mixed on-site by trained servers if the following conditions are met:

- (1) lower-potency hemp beverages do not contain any alcohol and are not served with alcohol;
- (2) drinks may contain only a hemp-derived cannabinoid emulsion mixed with two other ingredients such as a flavoring or carbonated water;
- (3) the hemp-derived cannabinoid emulsion must be dispensed with a calibrated pump. The accuracy of the pump must be verified through quarterly testing.
- (4) Procedures for mixing the beverage are developed to ensure consistent and accurate potency, and the servers are trained to the procedures. Records of the training must be maintained and provided to the office upon request.

9810.2600 – Delivery

Subpart 1. **General requirements.** A cannabis business holding a valid cannabis delivery license must establish a standard operating procedure to ensure compliance with Minnesota Statutes, Chapters 221, 342, and part 9810.1100. A cannabis business holding a valid delivery license must comply with all commercial vehicle requirements imposed by the Minnesota Department of Public Safety, the Minnesota Department of Commerce, and the Minnesota Department of Revenue.

Subp. 2. **Delivery limits.** A delivery driver may not transport more than \$5,000.00 worth of products on a single delivery route.

Subp. 3. **Operational requirements for delivery businesses.**

- A. Drivers of delivery vehicles must possess a valid license and be in good standing with the Minnesota Department of Public Safety.
- B. Any vehicle used by a cannabis delivery licensee must adhere to the following requirements:
 - (1) Vehicles used for delivery of cannabinoid products must be in working condition, with no defects that prevent the vehicle from being used in accordance with all applicable traffic and safety laws.
 - (2) All vehicles used for deliveries must have security systems in place to prevent theft of cannabinoid products.
 - (3) A cannabis delivery business must use a motor vehicle that is properly registered in the state of Minnesota to perform the transportation of products covered under this part.
 - (4) Carries the appropriate amount of insurance as required by the Minnesota Department of Transportation, Minnesota Department of Commerce, or applicable federal regulation.
- C. Drivers of delivery vehicles are only authorized to make qualified deliveries on behalf of a cannabis business with a retail license or endorsement to a customer who has paid for the product prior to the delivery.
- D. Each delivery must contain a manifest with the following requirements:
 - (1) identification information of customer, patient, or designated caregiver including:
 - a. name;
 - b. address of delivery;
 - c. form of photo ID provided; and

- d. identification number on the government issued identification of the customer, patient, or designated caregiver receiving the delivery;
 - (2) name of the delivery driver;
 - (3) time of departure from the cannabis business premise;
 - (3) time of delivery of cannabinoid products to customer, patient, or designated caregiver;
 - (4) types, amounts, weights, or other applicable information of delivered cannabinoid products;
 - (5) time of return to either the delivery business or the cannabis business where the sale was initiated.
- F. Deliveries must be made in person and received by the customer, patient, or designated caregiver whose name is on the order, and prior to taking physical possession of products, individuals receiving deliveries must:
- (1) display photo ID for identity verification by the delivery driver; and
 - (2) sign delivery records immediately prior to taking physical possession of the delivered product.
- G. A delivery driver must not release physical possession of an order if:
- (1) the delivery driver cannot verify the identification of the receiving customer, patient, or designated caregiver;
 - (2) the customer does not sign for the delivery;
 - (3) payment is not received prior to delivery; or
 - (4) evidence of registry enrollment was not provided prior to delivery.
- H. Failed deliveries must be reported immediately by the delivery driver to the cannabis business originating the sale. The delivery driver must ensure all products are returned to the retailer and provide details of the failed delivery, including:
- (1) the time the delivery was attempted; and
 - (2) the reason the delivery was not made.
- I. All deliveries must be updated in the designated statewide monitoring system.

Subp. 4. **Unordered products.** A delivery driver may not have any un-ordered regulated products in the delivery vehicle during a delivery route.

9810.2700 – Events

Subpart 1. **Duration.** Cannabis event shall last no more than four days. The first day shall be the initial day the cannabis event is open to the public. Every 24 hours after the first day shall be considered an additional day. The start time and end time of the event for each day shall be listed in the application under Minnesota Statutes, section 342.39, subdivision 2 and approved by the local government.

Subp. 2. **Secure storage area.**

- A. All cannabis plants, cannabis flower, cannabis products, lower-potency hemp edibles, hemp-derived consumer products sold at a cannabis event must be stored in a secure storage area that satisfies the applicable requirements under Minnesota Statutes, section 343.40, and part 9810.1500.
- B. All products for retail sale are held within a limited access area that restricts access to persons at least 21 years of age.
- C. All cannabis plants, cannabis flower, cannabis products, lower-potency hemp edible, and hemp-derived consumer products not on display, pursuant Minnesota Statutes, section 342.40, subdivision 6, are contained within a locked storage container that has a separate key or combination pad only accessible authorized personnel for the specific cannabis business.

Subp. 3. **On-site consumption areas.** All cannabis events licensed to permit on-site consumption must have:

- A. limited access to the consumption area, pursuant to Minnesota Statutes, section 342.40 subdivision 4;
- B. commercial grade fencing surrounding the entire perimeter of the consumption area.

Subp. 4. **Promotional items.**

- A. Cannabis flower or cannabis products must not be given to event attendees for no remuneration or to another cannabis business for the purpose of quality control.
- B. Vendors or event organizer licensees may provide cannabis paraphernalia and merchandise for no remuneration.

Subp. 6. **Authorized event retailer registration.** An applicant for an event license that will include retail sales must provide the office with the name and license number of any retailer that will make regulated products available for sale at the event,

Subp. 5. **Retail sales and record keeping.** An authorized event retailer must ensure that records of sales are updated in the statewide monitoring system within 24 hours.

9810.3000 – Testing Facility Standards

Subpart 1. **Incorporation by reference.** The ISO/IEC Standard 17025 is incorporated by reference and made a part of this rule where indicated.

Subp. 2. **Tasting facility inspection.** Laboratories must comply with all inspections by the office. All protocols and records which are required to be maintained per Minnesota Statutes, section 342.38 must be provided to the office upon request and readily available for inspection.

Subp. 3. **Testing facility reports.** A testing facility regulated under Minnesota Statutes, Chapter 342 must provide all information requested by the office regarding sample handling, testing facility practices, copies of relevant analytical records, and all other information required by the office relevant to determining compliance with Minnesota Statutes, Chapter 342 and these rules.

Subp. 4. **General operations.**

- A. A testing facility must operate formal management systems under the International Organization for Standardization (ISO) and obtain and maintain ISO 17025 accreditation through a laboratory accrediting organization.
- B. A testing facility may demonstrate analytical capability and acceptable performance through a combination of:
 - (1) existing certificates and approvals;
 - (2) documented demonstrations of analytical capabilities; or
 - (3) annual participation and passing performance in an ISO 17043-accredited proficiency testing program.
- C. A testing facility must maintain written standard operating procedures describing the actions to receive, prepare, and test all mandatory samples described in this section for each regulated product handled. Standard operating procedures must include:
 - (1) sample receipt;
 - (2) sample handling;
 - (3) Representative subsampling policies when the whole sample is not used for analysis;
 - (4) sample testing procedures; and
 - (5) sample testing acceptance criteria.
- D. A testing facility must maintain the identity and integrity of all samples handled from time of receipt by the testing facility or the reporting of analytical results and disposal of untested samples.

- E. A testing facility must notify the office in writing of any operational changes planned at least 30 days prior to the change occurring.

Subp. 5. **Prohibited activities.** A testing facility may not:

- A. misrepresent approvals from the office on any document or marketing material;
- B. refuse inspection of premises and related records by authorized representatives of the office;
- C. falsify, misreport, or misrepresent any testing data or test results to the office or to another cannabis businesses.

Subp. 6. **Approvals by the office.** A testing facility may seek approval to use specific procedures to test the allowable product types and analytes. To receive approval:

- A. A testing facility must specify one or more fields of testing for which it seeks approval. A testing facility must be approved for at least one field of testing to maintain an active license. A testing facility is not required to seek approval for all fields of testing.
- B. A testing facility must use analytical testing methodologies for the required safety tests prescribed by Minnesota Statutes, section 342.61 subd.2 and part 9810.3100 Subp.4 that are based upon published peer-reviewed methods, have been validated for cannabis testing by an independent third party, and have been internally verified by the licensed laboratory according to Appendix J or K of the AOAC International's Official Methods of Analysis, 22nd Edition, with guidance from published cannabis standard method performance requirements where available.
- C. Method validation procedures for testing methods must meet AOAC International validation guidelines.
- D. Method verification results must demonstrate sufficient specificity and sensitivity to meet the reporting limit requirements for each analyte for which the lab is approved.

Subp. 7. **Revocation conditions.** The office may revoke a testing facility's approval for any and all analytical methods when the testing facility has failed to:

- A. submit accurate application materials to the office as required in Minnesota Statutes, Chapter 342;
- B. comply with application requirements under Minnesota Statutes, Chapter 342;
- C. comply with all applicable laws, rules, standards, policies, and procedures; or
- D. failing to:

- (1) allow physical inspection of the testing facility by authorized representatives of the office; or
- (2) submit copies of inspection and corrective reports issued by the approved ISO/IEC 17025 accreditation body or proficiency testing program, as requested by the office.

Subp. 8. **Personnel, training, and oversight.** A laboratory must operate under the direction of at least one technical manager responsible for the laboratory achieving and maintaining the quality and analytical standards of practice. Only individuals who have demonstrated qualifications for the role through documented education and experience performing the required actions may be designated as a technical manager.

Subp. 9. **Record keeping.** In addition to all requirements under Minnesota Statutes, Chapter 342, and this rule, all testing facility data packages must be recorded in the statewide monitoring system and:

- A. be maintained for a minimum of three years; and
- B. include the following:
 - (1) a case narrative, written on cannabis testing facility letterhead that:
 - a. describes any sample receipt, preparation, or analytical issues encountered as well as any method non-conformances or exceedance of quality assurance and/or quality control criteria used by the cannabis testing facility;
 - b. identify the preparation and analytical methods utilized by the cannabis testing facility; and
 - c. a signed statement by an authorized cannabis testing facility representative as to the accuracy, completeness, and compliance with the methods of the results presented.
 - (2) chain-of-custody information or other paperwork indicating requested analyses and documentation of sample collection and receipt must be reported with the cannabis testing facility's results;
 - (3) a summary of analytical results, with sufficient data to evaluate the laboratory results, including a summary of laboratory quality assurance and/or quality control results; and
 - (4) a copy of the required sample result report.

Subp. 10. **Sample result reporting.**

- A. All samples received and processed by the testing facility must have a report completed.

- B. It should be noted whether the complete sample was homogenized and tested as received or if a portion was sampled by the testing laboratory for analysis.
- C. Measurement uncertainty and limits of detection and/or limits of quantitation must be reported with the results of testing batch samples of products.
- D. A certificate of the analysis must be provided to the sampling entity for the sample submitted for analysis that includes all the following information at minimum:
 - (1) name and license number issued by the office for testing facility conducting analysis;
 - (2) name and license number issued by the office for the entity submitting the sample;
 - (3) product category, product type, and name of product being sampled;
 - (4) product batch number represented by the sample;
 - (5) summary of analytical results including sample identifier, methods performed, target compounds, sample result, reporting limit, proper qualifier according to laboratory standard procedures, units of measure, preparation date(s), where applicable, and analysis date(s);
 - (6) for homogeneity and contaminant analysis, and indication of whether the analytical results meet the acceptance criteria established by the office.

Subp. 11. **Disposal.** Unanalyzed portions of samples must be disposed of according to part 9810.1200, unless the samples are being held subject to a request by the office or for stability testing.

Subp. 12. **Variance.**

- A. A testing facility licensed by the office may seek a variance from one or more parts of this chapter subject to this subpart.
- B. A request for a variance must contain the following:
 - (1) the rule part and language for which the variance is sought;
 - (2) reasons for the request;
 - (3) alternate measures that the laboratory will take if the office grants its request for variance;
 - (4) the proposed length of time of the variance; and
 - (5) data that the testing facility will provide to ensure analytical results of equal or better reliability, if applicable.
- C. The office shall evaluate the request for variance, and approve the request if:

- (1) the variance request contained the required information from item B;
 - (2) the variance will have no potential adverse effect on public health, safety, or the environment;
 - (3) the alternative measures to be taken, if any, are equivalent to or superior to those prescribed;
 - (4) strict compliance with the rule will impose an undue burden on the applicant or on the industry as a whole;
 - (5) the variance does not vary a statutory standard or preempt federal law or rule; and
 - (6) the variance has only future effect.
- D. If the office grants a variance, the effect of the variance is as follows:
- (1) any alternative measures or conditions attached to a variance approved by the office shall have the force and effect of law; and
 - (2) a violation of the alternative measures or conditions attached to a variance approved by the office shall subject this testing facility to the enforcement actions and penalties provided in law or rule.
- E. The office may deny, revoke, or refuse to renew a variance when the criteria in item C are not met or the additional measures or conditions in item D are not met.

9810.3100 – Product Testing and Product Sampling Protocols

Subpart 1. **Authorities of the office.** To ensure public health and safety the office may, at any time, require immediate mandatory testing of a regulated product suspected to be a potential human health hazard or threat to public safety.

Subp. 2 **Prohibited actions.** No person may offer any regulated product in its final packaging for wholesale distribution or retail sale which:

- A. has not undergone mandatory testing are required in this section; or
- B. does not meet the acceptance criteria established by the office for that product.

Subp. 3. **General.**

- A. Entities must maintain written standard operating procedures describing the actions to collect all mandatory samples described in this section for each regulated product handled. Standard operating procedures must:
 - (1) address all the requirements for sample and data collection and laboratory analysis described in this section;
 - (2) contain detail necessary for accurate and consistent actions by assigned staff; and
 - (3) contain process for supervisory observations to verify sample collection actions are completed accurately by assigned staff.
- B. Staff conducting sampling activities or sample testing must be knowledgeable in standard operating procedures necessary to perform actions accurately and consistently. Training records of such staff must be maintained for three years.

Subp. 4. **Testing methods.**

- A. The testing facility must grind the batch sample to create a representative and homogeneous composite batch sample for testing.
- B. The testing facility must grind a raw cannabis sample and may also use a paddle blender on all or part of the batch sample to produce a homogenous composite batch sample.
- C. All required testing must be performed on the composite batch sample.
- D. Complete homogenization of the entire submitted sample does not apply when homogeneity testing is to be performed.

Subp. 5. **Mandatory testing**

- A. All batches of regulated products must be tested to verify the following:

- (1) potency and stability of the cannabinoids for accuracy of mandatory labeling;
 - (2) homogeneity of the cannabinoids in each serving within the batch to meet the acceptance criteria established by the office and for accuracy of mandatory labeling;
 - (3) contaminant levels in all of the following categories do not exceed the acceptance criteria established by the office:
 - a. foreign material;
 - b. heavy metals;
 - c. microbiological contaminants;
 - d. mycotoxins;
 - e. pesticide residue; and
 - f. residual solvents.
- B. A relevant cannabis derived ingredient or hemp derived ingredient testing report may be used to meet any of the mandatory testing items required in this subpart when:
- (1) the production process of the cannabis consumer product does not reasonably introduce or enhance the potential for the contaminant category in the regulated product; or
 - (2) the handling of the product has not reasonably altered the stability, potency, or homogeneity of the regulated product.
- C. A product offered for sale is not required to be tested for a contaminant category when the hazard of that contaminant is not relevant to the product and supporting written documentation is available.
- D. Mandatory testing of batches may occur prior to the regulated product being packaged.
- E. All testing reports produced by the testing facility must be maintained for at least three years from the date of the report. Testing reports must be available for inspection by the office.

Subp. 6. Annual Report for Testing Thresholds.

- A. No later than July 1 of each year, the office must publish on its website an annual report for testing thresholds identifying:
- (1) approved analytical methods for contaminant tests under each category in subpart 4, item A, subitem 3, units a-f;

- (2) the specific contaminants listed in subpart 4, item A, subitem 3, units a-f required to be tested for each product type in part 9810.2100;
 - (3) the acceptance criteria by product category and contaminant type;
 - (4) analytical methods and acceptance criteria for homogeneity; and
 - (5) reporting requirements for the analytical test labs for each analyte and product category.
- B. Licensed testing facilities must ensure that their testing protocols and SOPs are updated to reflect any changes in the annual report no later than August 1 of each year.
- C. The office shall only amend the annual report for testing thresholds outside of the schedule in item A if the office determines an addition or revision is necessary to protect public health and safety.

Subp. 7. Sample collection methods.

- A. Methods for sample collection must ensure the accurate representation of the batch. Representation of the batch must be based upon rational established criteria such as random sampling and take into consideration:
- (1) statistical criteria for component variability, confidence levels, and degree of precision desired;
 - (2) inherent characteristics of the regulated product which may impact batch consistency;
 - (3) the quantity needed for specific laboratory analysis.
- B. Methods for sample collection must maintain the integrity of the sample to include:
- (1) sample containers, collection tools, and supplies do not alter the accuracy of the analysis;
 - (2) sample containers, collection tools, and supplies must be cleaned when necessary and handled in a manner to prevent introduction of contaminants into the sample;
 - (3) sample collection actions are performed in a manner visible to mandatory recording devices;
 - (4) sample containers must be opened, filled, and resealed in a manner designed to prevent contamination of their contents and contamination of other samples;
 - (5) sterile equipment, utensils and aseptic sampling techniques must be used when relevant for the analysis;

- (6) collected samples must be identified so that the following information can be determined: product name, the product batch number, the date on which the sample was taken, and the identity of the person who collected the sample;
- (7) sample containers are sealed immediately after collection in a manner to indicate when tampering has occurred, or the integrity of the sample has otherwise been compromised.

Subp. 8. **Responsibilities of license holder.** The license holder is responsible for the for ensuring the following:

- A. workers responsible for sample collection have been properly trained on sampling procedures;
- B. all mandatory testing is completed by a testing facility licensed by the office and approved for the analytical method specific to the product type being tested;
- B. the identity and integrity of all samples collected are maintained from time of collection to receipt by the testing facility or the licensed transporting entity; and
- C. complete and accurate disclosures are made to the testing facility of all cultivation and production methods required in Minnesota Statutes, section 342.61 subd. 4, or other relevant information necessary for the accurate laboratory analysis and reporting of analytical results.

Subp. 9. **Remediation.**

- A. All batches of regulated product failing to meet acceptance criteria for contaminants categories or homogeneity established by the office must be:
 - (1) disposed of according to the part 9810.1200; or
 - (2) remediated according to a plan approved by the office.
- B. Remediation plans must be in writing and submitted on the forms prescribed by the office.
- C. No batch tested product may undergo remediation activities until the office approves the submitted plans.
- D. All product awaiting remediation or disposal must be identified and quarantined to prevent use other than through disposal or approved remediation plan.
- E. All remediated material must meet appropriate acceptance criteria, standards, specifications, and any other relevant criteria established by the office as part of the approved remediation plan.

Subp. 10. **Mandatory notifications.**

- A. A license holder whose product fails to meet mandatory testing criteria must report all notifications of non-compliant laboratory analysis to the office and include the following information:
 - (1) the mandatory testing criteria that was not met;
 - (2) the production status of the batch represented; and
 - (3) the decision to dispose of product or of the intent to remediate the batch pursuant to part 9810.3100, subpart 8.
- B. Notifications are required for all testing results of regulated products and is not limited to batches which have completed production processes.

Subp. 11. **Research and development.** Cannabis flower and cannabis product batches which are produced solely for the purposes of research and development by a cannabis microbusiness licensed under Minnesota Statutes, section 342.28, subd. 1a, are not required to meet the provisions of this section provided that no human consumption occurs.

9810.4000 – Medical Cannabis Patient Registry, Patient Enrollment

Subpart 1. **Registry enrollment application for patients.** To enroll in the medical cannabis patient registry, an applicant, an applicant's parent or legal guardian, or an applicant's spouse must apply for the registry on forms provided by the office that meet the requirements of Minnesota Statutes, section 342.52, subdivision 2, including signed disclosures.

Subp. 2. **Proof of Minnesota residency.** An applicant must provide proof of Minnesota residency. If an applicant is a minor or person subject to guardianship, the applicant's parent or legal guardian must provide proof of Minnesota residency. Proof of Minnesota residency can be established by providing the following to the office:

- A. one of the following issued by Minnesota Driver and Vehicle Services: a valid, unexpired copy of a Minnesota driver's license, instruction permit, or identification card; or
- B. a valid, unexpired copy of another state, federal, or tribal government-issued photo identification card and at least one form of other documentation that contains the name and current address of the applicant or the applicant's parent or legal guardian and indicates Minnesota residency.

Subp. 3. **Alternative registry enrollment application for veterans.** The office must make available on its website a Veteran Registry Application Form that collects all required information under Minnesota Statutes, section 342.52, subd. 3, and must enroll in the medical cannabis registry any veteran that submits to the office:

- A. a signed and completed Veteran Registry Application Form;
- B. proof of Minnesota residency by providing the documentation described in subpart 2; and
- C. a copy of the applicant's veteran identification card.

Subp. 4. **Patient application review.** The office must review applications for completeness and any basis of denial. When a patient application is deemed complete and no basis for denial exists under Minnesota Statutes, section 342.52, subdivision 4, the office must approve a qualifying applicant and enroll the patient in the medical cannabis registry. The office must notify the patient, or caregiver, if applicable, of approval or denial of the patient's application. If approved, the office must issue the patient a unique registry number. If denied, the office must provide written notice to the patient including all reasons for denying enrollment.

Subp. 5. **Suspension of patient enrollment.** The office must suspend the registration of a patient if the patient provided false, misleading, or incorrect information to the office. The patient's registration must be suspended until the information is corrected and the office makes an eligibility determination.

Subp. 6. **Revocation of patient enrollment.**

- A. The office may revoke patient registration under the following circumstances:

- (1) the patient fails to submit certification from a health care practitioner that the patient is currently diagnosed with a qualifying medical condition;
 - (2) if the patient is a veteran, the patient fails to submit confirmation that the patient is currently diagnosed with a qualifying medical condition in a form and manner consistent with the veterans' application;
 - (3) the patient's certifying health care practitioner files a declaration that the patient's qualifying diagnosis no longer exists, and the patient does not submit another certification within 30 days of the health care practitioner's declaration, pursuant to Minnesota Statutes, section 342.52, subdivision 2(c);
 - (4) the patient discontinues regularly scheduled treatment for their qualifying medical condition from their health care practitioner;
 - (5) the patient fails to report changes in their qualifying medical condition to their health care practitioner;
 - (6) the office has reason to believe or has received evidence of the patient intentionally selling or diverting medical cannabis flower or medical cannabis products in violation of Minnesota Statutes, Chapter 342; or
 - (7) the office receives notice of the patient's death.
- B. Except under subitem 7, the office must provide notice of revocation to the patient, and as applicable, the patient's health care practitioner, and reasons for revoking the patient's registration. If the patient's enrollment in the registry program is revoked under paragraphs D or E, the patient may re-apply for enrollment 12 months after the date on which the patient's enrollment was revoked.

Subp. 7. **Enrollment renewal.** Patients wishing to renew their registration must do so every three years after their enrollment date using forms provided by the office.

9810.4001 – Medical Patient Registry, Caregiver Enrollment

Subpart 1. **Registered designated caregiver application and approval.** To be approved as a patient’s registered designated caregiver, an applicant must apply for registration on forms provided by the office. The office must review applications for completeness and approve applicants if the office determines that no basis for denial exists under Minnesota Statutes, section 342.52, subdivision 9.

Subp. 2. **Parents, legal guardians, and spouses acting as caregivers.** A patient’s parent, legal guardian, or spouse may act as the patient’s caregiver and be designated as such in the registry. The patient, the patient’s parent, legal guardian, or spouse must if notify the office and provide documentation of the patient-caregiver relationship on forms provided by the office.

Subp. 3. **Registered designated caregivers; responsibilities.** A registered designated caregiver must:

- A. notify the office of any name or address change within 30 days of the change;
- B. notify the office within ten calendar days following the death of the designated caregiver's patient; and
- C. dispose of all unused medical cannabis flower, medical cannabinoid product, or associated medical cannabis paraphernalia using the methods described in subpart 5, as soon as possible, but no later than 10 days of:
 - (1) the mandatory testing criteria that was not met;
 - (2) medical cannabis flower or medical cannabinoid product recall.

Subp. 4. **Registered designated caregivers; authorized actions.** A registered designated caregiver may:

- A. transport the patient to and from a licensed cannabis business;
- B. obtain and transport an adequate supply of medical cannabis flower or medical cannabinoid products from a licensed cannabis business on behalf of the patient;
- C. prepare medical cannabis flower or medical cannabinoid products for self-administration by the patient;
- D. administer medical cannabis flower or medical cannabinoid products to the patient;
- E. on behalf of the patient, complete any available patient self-evaluations or other surveys;
- F. on behalf of the patient, notify the office of any change of patient name or address within 30 business days of the change;
- G. participate in the registry program as a patient if approved by the office using the process outlined in Section PATIENT ENROLLMENT subparts 1 to 4; and

- H. cultivate up to eight cannabis plants on behalf of one patient household at the caregiver's home.

Subp. 5. **Home cultivation of cannabis on behalf of patient.** If a patient directs their designated caregiver to cultivate cannabis plants on behalf of their household, the patient must notify the office that the patient has assigned their right to cultivate cannabis plants for adult use to their designated caregiver. The patient may revoke such assignment by notifying the office. The caregiver shall not cultivate more no more than four being mature, flowering plants at a time for the patient.

Subp. 6. **Registered designated caregivers; prohibited actions.** A registered designated caregiver must not:

- A. consume, by any means, medical cannabis flower or medical cannabinoid products that have been dispensed on behalf of the patient; or
- B. sell, provide, or otherwise divert medical cannabis flower or medical cannabinoid products that have been dispensed for a patient.

Subp. 7. **Suspension of designated caregiver registration.** The office must suspend registration of a registered designated caregiver under the following circumstances:

- A. the office as reason to believe the designated caregiver is serving more than six patient households at a time. Patients who reside in the same residence are considered one patient.
- B. the office has reason to believe the designated caregiver provided false, misleading, or incorrect information to the office;
- C. the office has reason to believe the patient is being mistreated; or
- D. the office received a patient complaint.
- E. The designated caregiver's registration must be suspended until the above circumstances have been cured and the office makes an eligibility determination.

Subp. 8. **Revocation of designated caregiver registration.** The office must revoke the registration of a designated caregiver under the following circumstances:

- A. the office has reason to believe the designated caregiver is misusing or diverting medical cannabis flower or medical cannabinoid products; or
- B. the office received a request by the patient.

Subp. 9. **Disposal of medical cannabis.** Medical cannabis flower or medical cannabinoid products must be disposed of by one of the following methods:

- A. depositing it with a licensed cannabis business; or

- B. rendering it non-retrievable and disposed of in a manner consistent with applicable state and local solid waste laws.

Subp. 10. **Qualifying patient and designated caretaker responsibilities.** A qualifying patient or designated caregiver who is no longer registered with the medical cannabis patient registry must not transfer, share, give, sell, or deliver any unused medical cannabis in their possession to any other person, regardless of whether the person is participating in the medical cannabis patient registry program. A qualifying patient or designated caregiver who is no longer registered with the medical cannabis patient registry must, within ten calendar days after the patient or caregiver ceases to be registered or eligible, dispose of any unused medical cannabis in their possession by one of the following methods by:

- A. depositing it with a medical cannabis distribution site located in Minnesota;
- B. depositing it with a law enforcement agency having local jurisdiction for destruction;
- C. disposing of the medical cannabis at a government recognized drug take-back program located in Minnesota; or
- D. rendering it nonrecoverable consistent with part 9810.1200.

9810.4003 – Medical Cannabis Patient Registry, Healthcare Practitioner Qualifications and Duties

Subpart 1. **Health care practitioner qualifications.** Except for patients who are veterans, the office may only accept electronic certifications of a patient’s qualifying medical condition(s) for the therapeutic use of medical cannabis from health care practitioners who hold an active license, in good standing, under Minnesota Statutes, Chapter 147 for physicians, under Minnesota Statutes, Chapter 147A for physician assistants, or Minnesota Statutes, sections 148.171 to 148.285, for advanced practice registered nurses.

Subp. 2. **Health care practitioner requirements.** Before issuing an electronic certification of a patient’s qualifying medical condition(s), a health care practitioner must:

- A. have a prior or ongoing medical relationship between the health care practitioner and patient;
- B. assess the patient's medical and family history and current medical condition, which includes:
 - (1) an examination of the patient and medical and family history appropriate to confirm the diagnosis of the qualifying medical condition(s). This examination may be conducted remotely by secure videoconference, telephone, or other remote means; and
 - (2) communicate, as appropriate with subspecialists also treating the patient;
- C. determine, in the health care practitioner's medical judgment, whether a patient has a qualifying medical condition(s) and, if so determined, provide the patient with the certification of that diagnosis;
- D. advise patients, registered designated caregivers, and parents, legal guardians, and spouses acting as caregivers of any nonprofit patient support groups or organizations;
- E. provide to patients explanatory information from the office, including information about the therapeutic use of cannabis, including the possible risks, benefits, and side effects of the proposed treatment;
- F. advise patient on potential drug-drug interaction with current medications;
- G. advise patient on potential risks of cannabis use specific to the patient’s medical condition and history; and
- H. agree to continue treatment of the patient's qualifying medical condition(s) and to report findings to the office.

Subp. 3. **Health care practitioner duties.** When the health care practitioner receives notice from the office that a patient has been enrolled in the registry program, the health care practitioner must:

- A. participate in the patient registry reporting system as established by the office for each patient for whom the practitioner has written a certification of qualifying medical condition(s). A health care practitioner must transmit patient data as required by Minnesota Statutes, section 342.55, subdivision 4;

- B. be available to provide continuing treatment of the patient's qualifying medical condition(s);
- C. maintain and report health records under subpart 6 for all patients for whom the practitioner has issued a written certification that supports the certification of the qualifying medical condition(s);
- D. make a copy of the records that support the certification of the qualifying medical condition(s) available to the office, and otherwise provide information to the office upon request about the patient's qualifying medical condition(s), course of treatment, and pathological outcomes to ensure compliance with relevant sections of Minnesota Statutes, Chapter 342 and related administrative rules;
- E. every three years, if the patient wishes to continue their enrollment in the registry, assess whether the patient continues to have the qualifying medical condition(s) or conditions and, if so, issue the patient a new certificate of that diagnosis; and
- F. notify the office, in a manner prescribed by the office, in writing within 14 calendar days of learning of the death of a patient whose qualifying medical condition(s) was certified by the health care practitioner.

Subp. 4. **Certification of a qualifying medical condition.** A certifying health care practitioner must complete an electronic certification of a patient's qualifying medical condition(s) on a form provided by the office. The written certification must:

- A. acknowledge that the patient is under the health care practitioner's care, either for the patient's primary care or for the qualifying medical condition(s);
- B. confirm the patient's diagnosis of the qualifying medical condition(s);
- C. contain an affirmation that the health care practitioner has:
 - (1) established a patient-provider relationship;
 - (2) conducted an examination appropriate to confirm the diagnosis; and
 - (3) reviewed the patient's medical and family history to confirm the diagnosis is within the health care practitioner's professional standards of practice; and
 - (4) consult the patient on potential drug-drug interactions and appropriateness of cannabis use in consideration of the patient's medical and family history;
- D. include the date the certification of the qualifying medical condition(s) was made; and
- E. include any additional information the office requests to assess the effectiveness of medical cannabis in treating the qualifying medical condition(s) or associated symptoms.

Subp. 5. **Health care practitioner prohibitions.** A health care practitioner who has issued or intends to issue a written certification of a patient's qualifying medical condition(s) must not:

- A. advertise as a retailer or producer of cannabis flower or cannabis products;

- B. knowingly refer patients to a cannabis business or to a designated caregiver;
- C. issue certifications while holding a financial interest in a cannabis business;
- D. issue a written certification for their participation in the registry program;
- E. directly or indirectly accept, solicit, or receive anything of value from a licensed cannabis business, licensed hemp business, an employee thereof, a manufacturer, or any other person associated with the licensed cannabis or hemp business;
- F. offer a discount or any other thing of value to a patient who uses or agrees to use a particular registered designated caregiver, licensed cannabis business or hemp business, or medical cannabis flower or medical cannabinoid products; or
- G. directly or indirectly benefit from a patient obtaining a written certification for the qualifying medical condition(s). Such prohibition does not prohibit a health care practitioner from charging an appropriate fee for the patient visit;
- H. hold a financial or management interest in an enterprise that produces, sells, or provides cannabis flower or cannabis products; or
- I. perform examinations for the certification of qualifying medical conditions, or complete certifications of qualifying medical conditions at the location of any cannabis business.

Subp. 6. **Records maintained by the health care practitioner.** A health care practitioner must maintain a health record for each patient for whom the health care practitioner has certified the qualifying medical condition(s) for at least three years after the last patient visit, or seven years, whichever is greater. These records need not be maintained separately from the health care practitioner's established records for the ongoing medical relationship with the patient. The records must be legible, accurately reflect the patient's evaluation and treatment, and must include the following:

- A. the patient's name and dates of visits and treatments;
- B. the patient's case history as it relates to the qualifying medical condition(s);
- C. the patient's health condition as determined by the health care practitioner's examination and assessment;
- D. the results of all diagnostic tests and examinations as they relate to the qualifying medical condition(s); and any diagnosis resulting from the examination;
- E. the patient's plan of care, which must state with specificity the patient's condition, functional level, treatment objectives, medical orders, plans for continuing care, and modifications to that plan; and
- F. a list of drugs prescribed, administered and dispensed, and the quantity of the drugs.

Subp. 7. **Health care facilities; storage policy.** Health care facilities licensed under Minnesota Statutes, Chapter 144A; hospice providers licensed under Minnesota Statutes, Chapter 144A; boarding care homes or supervised living facilities licensed under Minnesota Statutes, section 144.50; assisted living facilities under Minnesota

Statutes, Chapter 144G; facilities owned, controlled, managed, or under common control with hospitals licensed under Minnesota Statutes, Chapter 144; and other health care facilities licensed by the commissioner of health or the commissioner of human services may adopt reasonable restrictions on the use of medical cannabis flower or medical cannabinoid products by a patient enrolled in the registry program who resides at or is actively receiving treatment or care at the facility.

Subp. 8. **Health care facilities; return of items.** Upon discharge, transfer, or death of a patient, the health care facility must return all medical cannabis flower or medical cannabinoid products to the patient or other person authorized to possess it. If the health care facility is unable to return the remaining medical cannabis flower or medical cannabinoid products to the patient or other authorized person, the facility must destroy the medical cannabis flower or medical cannabinoid products in a manner consistent with part 9810.4001.

9810.4100 – Medical Cannabis Consultant Program

Subpart 1. **Medical cannabis consultant certificate application.** An applicant for a medical cannabis consultant certificate must submit to the office:

- A. a complete initial application on forms provided by the office;
- B. certificate of successful completion from an approved training program;
- C. proof of being age 21 or older pursuant to Minnesota Statutes, section 342.27, subdivision 4(b) for acceptable forms of identification. Acceptable forms of proof are a copy of the applicant's valid driver's license or other government-issued identification card, United States passport, or certified birth certificate; and
- D. any other documentation required by the office for the purpose of this program.

Subp. 2. **Consultation limitations.** A certificate holder may only provide services when acting on behalf of a licensed cannabis business holding a valid medical cannabis retail endorsement under Minnesota Statutes, section 342.51, as an employee.

Subp. 3. **Certified medical cannabis consultant; authorized actions.** A certificate holder may:

- A. perform regular job duties and business functions as permitted by the business; and
- B. assist an enrolled patient, registered designated caregiver, or the patient's parent, legal guardian, or spouse acting as a caregiver with the following:
 - (1) selection of medical cannabis flower, medical cannabinoid products, and associated paraphernalia sold at the cannabis business that may treat or alleviate the enrolled patient's qualifying medical condition or associated symptoms;
 - (2) understanding the risks and benefits of medical cannabis flower, medical cannabinoid products, and associated paraphernalia sold at the cannabis business;
 - (3) understanding the potential pharmacological impacts and risks associated with cannabis use and other common pharmacological drugs;
 - (4) understanding the risks and benefits of methods of administration of medical cannabis flower and medical cannabinoid products;
 - (4) advice about the safe handling and storage of medical cannabis flower and medical cannabinoid products, including strategies to reduce access by minors; and
 - (5) instruction and demonstration of proper use and administration/application of medical cannabis flower and medical cannabinoid products.

Subp. 4. **Certified medical cannabis consultant; responsibilities.** When discussing a cannabis product with an enrolled patient, registered designated caregiver, or the patient's parent, legal guardian, or spouse acting as a caregiver, a certificate holder must refer to the medical cannabis flower and medical cannabinoid products using

the cannabinoid profile labeling required by Minnesota Statutes, section 342.63, in addition to the represented strain name, as applicable.

Subp. 5. **Certified medical cannabis consultant; prohibited actions.** A certificate holder shall not:

- A. offer or undertake to diagnose or cure any human or animal disease, ailment, injury, infirmity, deformity, pain, or other condition, physical or mental, real or imaginary, by use of medical cannabis flower or medical cannabinoid products or any other means or instrumentality;
- B. recommend or suggest modification or elimination of any course of treatment that does not involve the therapeutic use of medical cannabis flower or medical cannabinoid products;
- C. solicit or accept any form of remuneration directly or indirectly, overtly or covertly, in cash or any other form in return for recommending a certain product, manufacturer, retailer, designated caregiver, or health care practitioner;
- D. provide free samples of medical cannabis flower or medical cannabinoid products to a patient unless the cannabis business also holds a valid on-site consumption endorsement;
- E. allow a patient to consume medical cannabis flower or medical cannabinoid products on the premises unless the cannabis business also holds a valid on-site consumption endorsement.

Subp 6. **Display of certificate.** A photocopy of the certificate of the medical cannabis consultant(s) employed by the cannabis business must be displayed in a place and manner visible to customers in each retail location while the consultant is providing services for the business.

Subp. 7. **Denial, suspension, and revocation of certificate.** The office may deny, suspend, or revoke a certificate if:

- A. the certificate was procured through fraud, misrepresentation, or deceit; or
- B. the applicant or certificate holder has violated any part of Minnesota Statutes, Chapter 342, or this section.

Subp. 8. **Denial, suspension, and revocation of certificate; procedure.** The office will provide written notice of the office's denial, suspension, or revocation of a certificate. If the applicant or certificate holder believes the information in the office's written notice of denial, suspension, or revocation of the certificate is in error, the applicant or certificate holder may ask the office to reconsider the parts of the order that are alleged to be in error. The request for reconsideration must be in writing, delivered to the office by certified mail within seven calendar days after receipt of the order, and provide documentation to support the allegation of error. The office must respond to a request for reconsideration within calendar 15 days after receiving the request. The office's disposition of a request for reconsideration is final.

Subp. 9. **Certificate renewal.** Certificates must be renewed every three years. Failure to receive a courtesy renewal notice does not relieve or exempt the renewal requirement. Certificate holders must submit the following to the office:

- A. a complete renewal application on forms provided by the office; and

- B. proof of successful completion of an office approved training program prior to renewal.

Subp. 10. **Name and address changes.** It is the responsibility of each certificate holder to maintain their correct name and address on file with the office. Requests for name and address changes must be submitted in writing to the office. Certificate holders requesting a name change must also provide documentation showing the name was legally changed with their written notice.

Subp. 11. **Expired certificate.** A certificate holder must not provide medical cannabis consultant services while their certificate is expired. The certificate is expired if the certificate holder does not renew on or before the expiration date. If the certificate has been expired for more than one year, the certificate holder must:

- A. complete a renewal application form;
- B. provide proof of successful completion of required continuing education since certificate expiration, or, if the certificate has been expired for more than three years, proof the certificate holder re-took and successfully completed an approved training program; and
- C. provide any other documentation required by the office.

Subp. 12. **Approval of training program.** The office will consider for approval any training program which meets the requirements as outlined in this section. The authorized representative of the training program shall request approval on an application provided by the office. The application for approval of a training program must include, but is not limited to, documentation required by the office related to:

- A. detailed syllabus, including topics on drug interaction;
- B. identification and qualifications of instructors;
- C. training locations and facilities;
- D. outline of curriculum plan specifying all subjects, and the length in hours each subject is taught;
- E. duration of at least 30 hours of class time;
- F. class objectives;
- G. whether the training will be provided in-person or electronically;
- H. methods of evaluating the course and instructors by the training program and training participants;
- I. policies and procedures for maintaining training and testing records; and
- J. a sample of the training program's certificate of successful completion. At minimum, the certificate must contain the following information:
 - (1) name and contact information of the training program;
 - (2) name of the student; and
 - (3) date the student successfully completed the program.

Subp. 13. **Notice of change.** The authorized representative of an approved training program shall notify the office in writing of all changes with respect to information provided in the application, including changes in instructors or the instructor's credential status, within 30 days of such changes.

Subp. 14. **Renewal of an approved training program.** Training programs approved under this section must:

- A. reapply for approval from the office every three years through the same process for initial approval described in subpart 12; and
- B. comply with any changes to this section or training standards and guidelines in order to maintain an approved status.

Subp. 15. **Closure of an approved training program.** When a training program approved under this chapter closes, it shall notify the office in writing, stating the reason and the date of intended closing.

9810.4200 – Medical Cannabis Combination Business

Subpart 1. **Integrated facilities.** A medical cannabis combination facility may perform any cannabis activities for sale into the adult-use or medical cannabis market in the same facility so long as the activity performed is designated for only one market. A medical combination business shall not comingle adult-use cannabis flower or cannabis products and medical cannabis flower and medical cannabinoid products. A medical combination business seeking to cultivate medical and adult-use cannabis in the same facility must comply with part 9810.2000, subpart 14.

Subp. 2. **Annual verification and authorization procedure.** No later than 45 days after a medical cannabis combination business's license renewal application has been approved, the office must issue a letter verifying the businesses prior year medical cultivation canopy and sales into the medical cannabis market and notify the business of the amount of canopy it may cultivate for sale into the adult-use cannabis market.

- A. In order to verify the amount of canopy used to sell into the medical cannabis market, the office will verify the following:
 - (1) business's most recent cultivation plan submitted pursuant to part 2100, subpart 3, identifying the amount of the business dedicated to plant canopy;
 - (2) business's sales of medical cannabis flower and medical cannabinoid products to other cannabis businesses;
 - (3) business's sales of medical cannabis flowers and medical cannabinoid products to medical registry participants;
 - (4) if the medical cannabis combination business has previous cultivated adult-use cannabis under Minnesota Statutes, section 342.515, the business's sales of cannabis flower and cannabis products to other cannabis businesses; and
 - (5) if the medical cannabis combination business has previous cultivated adult-use cannabis under Minnesota Statutes, section 342.515, the business's sales of cannabis flowers and cannabis products to adult-use consumers.
- B. The office must annually determine the amount of canopy that a medical cannabis combination business has utilized to sell into the medical cannabis market in the preceding year.
 - (1) To determine utilized canopy in the first year the medical cannabis combination business is licensed, the office must:
 - a. make four inspections of the cultivation facility to determine the total amount of canopy space identified for cultivation on the cultivation plan that contains mature, flowering plants. The average square footage of these four visits shall constitute the first year observed medical canopy;
 - b. determine, through the statewide monitoring system the total amount of medical cannabis flower and medical cannabinoid products sold during the first year; and,

- c. calculate the medical canopy ratio (defined term?) by dividing the amount of medical product sales by the observed medical canopy.
 - (2) To determine utilized canopy in subsequent years, the office must:
 - a. determine, through the statewide monitoring system, the total amount of medical cannabis flower and medical cannabinoid products sold during the prior year;
 - b. calculate the total medical canopy used by multiplying the medical canopy ratio by the prior years medical sales; and
 - c. calculate one-third of the medical canopy for use as the adult-use canopy.
- C. Based on the determination in item B, the office will issue an authorization to each business stating the total canopy that the business may use to cultivate adult-use cultivation.
- D. If a medical cannabis combination business believes the office has miscalculated the medical canopy ratio it may, within 30 days of receiving the letter described in this subpart, request a review. If a medical cannabis combination business believes that the medical canopy ratio is inaccurate based on changed circumstances, it may request, no more than once per five years, that the office re-establish the ratio through the process described in item B (1), except that on inspection, the office may only measure those cultivation areas containing medical cannabis.

9810.5000 – Local Governments

Subpart 1. **Expedited complaints.** A local government that believes a licensed cannabis business within its jurisdiction is in violation of Minnesota Statute, Chapter 342 or these rules may request an inspection by the office by giving the office notice, via the online complaint form. If the online complaint form is offline, a local government may submit an email complaint to the chief regulatory officer.

Subp. 2. **Complaint process.**

- A. Standard complaints. A local unit of government may file an expedited complaint with the office using the complaint method identified on the office’s website. The office shall issue to the local unit of government an expedited complaint report, once the office’s investigation is complete, detailing its findings. If the office determines that an inspection is not necessary, it shall notify the local unit of government of that decision as part of its expedited complaint report.
- B. Suspension of registrant/licensee. If a local unit of government suspends a cannabis or hemp business’s retail registration, it must notify the office using the reporting method identified on the office’s website. The office shall issue to the local unit of government a suspension of registration review report, once the office’s investigation is complete, detailing its findings.

Subp. 3. **Retail registration caps.** Pursuant to Minnesota Statutes, sections 342.13(h) to 342.13(j), a local unit government may, but are not required to, limit the number of retail registrations issued within its jurisdiction. For purposes of determining a cap:

- A. The population of a city and county shall be determined the most recent population estimates from the Minnesota state demographer
- B. A city that delegates its authority to issue retail registrations under Minnesota Statutes, section 342.22, subd. 1, must notify the office on the form provided on its website.
- C. A local unit of government may include in its count of active retail registrations any retail locations operating under:
 - (1) tribal compact entered into under Minnesota Statutes, section 3.9224 or 3.9228; or
 - (2) a tribally issued license or registration.

Subp. 4. **Local approval.** Local units of government responsible for issuing retail registrations must:

- A. notify the office of the person, persons, or officer designated to provide the office notice of local approval through the state’s online licensing system; and
- B. notify the office of any delegation of registration authority under Minnesota Statutes, section 342.22.