Minnesota Department of Health

Adopted Exempt Permanent Rules Relating to Dried Raw Cannabis

4770.0200 DEFINITIONS.

[For text of subparts 1 to 5, see Minnesota Rules]

Subp. 5a. **Audit sample.** "Audit sample" means a representative sample necessary to complete audit testing of plant material, a dried raw cannabis batch, or a dried raw cannabis finished good collected for audit testing under part 4770.3035.

Subp. 6. **Batch.**

A. "Batch" means a specific quantity of medical cannabis, including a set of plants of the same variety of medical cannabis that have been grown, harvested, and processed together and exposed to substantially similar conditions throughout cultivation and processing, that:

(1) is uniform and intended to meet specifications for identity, strength, purity, and composition~~, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling batch record.~~; and

(2) is produced according to a single batch production record executed and documented during the same cycle of manufacture.

B. A batch of dried raw cannabis may not exceed 80 pounds.

[For text of subpart 7, see Minnesota Rules]

Subp. 7a. **Batch sample.** "Batch sample" means a representative sample taken from a batch of dried raw cannabis prior to laboratory testing.

[For text of subpart 8, see Minnesota Rules]

Subp. 8a. **CBD.** "CBD" means the compound cannabidiol, CAS number 13956-29-1.

Subp. 8b. **CBDA.** "CBDA" means cannabidiolic acid, CAS number 1244-58-2.

[For text of subpart 9, see Minnesota Rules]

Subp. 9a. **Chemical composition.** "Chemical composition" means the distribution of individual components within a final formulation or finished good. This includes active ingredients, inactive ingredients, and other ingredients. Active ingredients include cannabinoids used to define a finished good in the registered products list. The concentration of each active ingredient may be given either in terms of milligram per milliliter (mg/mL) for liquids and milligram per gram (mg/g) for solids or in terms of mass fraction (weight percentage).

[For text of subpart 10, see Minnesota Rules]

Subp. 10a. **Crop input.** "Crop input" means a substance other than water that is applied to or used in the cultivation of a cannabis plant for pest control, plant health, or growth management. Crop input includes pesticides, fungicides, plant regulators, fertilizers, and other agricultural chemicals regulated by the Minnesota Department of Agriculture.

[For text of subparts 11 to 14, see Minnesota Rules]

Subp. 14a. **Dried raw cannabis.** "Dried raw cannabis" means the dried leaves and flowers of the mature cannabis plant. Dried raw cannabis includes pre-rolled cannabis as long as the pre-roll consists of only dried cannabis leaves and flowers, an unflavored rolling paper, and a filter or tip. Dried raw cannabis does not include the cannabis seeds, seedlings, stems, stalks, roots, or any part of the immature cannabis plant.

[For text of subparts 15 and 16, see Minnesota Rules]

Subp. 16a. **Finished good.** "Finished good" means either an extract formulation that has been packaged and labeled for delivery to a medical cannabis distribution facility for distribution to patients or dried raw cannabis that has been packaged and labeled for delivery to a medical cannabis distribution facility.

Subp. 16b. **Flower.** "Flower" means the flower of the cannabis plant.

[For text of subpart 17, see Minnesota Rules]

Subp. 17a. **Immature plant.** "Immature plant" means a nonflowering cannabis plant that is no taller than eight inches and no wider than eight inches produced from a cutting, clipping, or seedling and is in a cultivation container.

[For text of subparts 18 and 19, see Minnesota Rules]

Subp. 19a. **Labeling.** "Labeling" means all labels and other written, printed, or graphic matter on a packaged finished good or any container or wrapper accompanying the packaged finished good.

[For text of subparts 20 to 23, see Minnesota Rules]

Subp. 24. **Manufacturing or manufacture.** "Manufacturing" or "manufacture" means the planting, cultivation, growing, and harvesting of cannabis and the process of converting harvested cannabis plant material into medical cannabis.

[For text of subparts 25 and 26, see Minnesota Rules]

Subp. 26a. **Medical cannabis brand name.** "Medical cannabis brand name" means the name under which a medical cannabis concentrate, a medical cannabis concentrate formulation, or a dried raw cannabis product is marketed and distributed.

Subp. 26b. **Medical cannabis concentrate.** "Medical cannabis concentrate" means a specific subset of medical cannabis that is produced by extracting cannabinoids from plant material. Categories of medical cannabis concentrate include products created using water-based, solvent-based, heat-based, or pressure-based extraction methods. Medical cannabis concentrate includes medical cannabis concentrate intended for use with a vaporizer delivery device or pressurized dose inhaler.

Subp. 26c. **Medical cannabis concentrate formulation.** "Medical cannabis concentrate formulation" means a liquid, including oil, a pill, or any other formulation type approved by the commissioner under Minnesota Statutes, sections 152.22, subdivision 6, paragraph (a), and 152.27, subdivision 2, paragraph (b), infused with medical cannabis and other ingredients that will be packaged into a finished good without further change and is intended for use or consumption other than by smoking. Medical cannabis concentrate formulation includes oral suspensions, tinctures, lotions, ointments, and any other medical cannabis delivery method approved by the commissioner.

[For text of subparts 27 to 33, see Minnesota Rules]

Subp. 33a. **Plant regulator.** "Plant regulator" has the meaning given in Minnesota Statutes, section 18B.01, subdivision 20.

Subp. 33b. **Pre-roll.** "Pre-roll" means any combination of flower, shake, or leaf rolled in unflavored paper and intended to be smoked.

[For text of subparts 34 to 36, see Minnesota Rules]

Subp. 36a. **Registered finished goods list.** "Registered finished goods list" means the official list maintained by the commissioner of finished goods permitted to be dispensed within the registry. The manufacturer must provide the commissioner the finished good's chemical composition, the total volume or weight of each active ingredient, storage instructions, and estimated expiration date. If a finished good will be dispensed in an amount larger than one unit or dose, the manufacturer must specify the volume or weight and chemical composition that constitutes a single dose.

[For text of subparts 37 and 38, see Minnesota Rules]

Subp. 38a. **Remediation.** "Remediation" means any process that removes or reduces the level of contaminants in a batch of dried raw cannabis flower and trim, either through extraction of oils or other means.

[For text of subpart 39, see Minnesota Rules]

Subp. 39a. **Rinsate.** "Rinsate" means a dilute mixture of a crop input or crop inputs with water, solvents, oils, commercial rinsing agents, or other substances that is produced by or results from the cleaning of crop input application equipment or containers.

Subp. 39b. **Shake.** "Shake" means pieces of a cannabis flower that were once part of larger buds.

[For text of subpart 40, see Minnesota Rules]

Subp. 41. **THC.** "THC" means tetrahydrocannabinol, CAS number 1972-08-3.

Subp. 42. **THCA.** "THCA" means tetrahydrocannabinolic acid, CAS number 23978-85-0.

Subp. 43. **Total cannabinoid content.** "Total cannabinoid content" means the combined target values by weight of all cannabinoids defining a finished good in the registered finished goods list, not including cannabinoids present only in trace amounts.

Subp. 44. **Total CBD content.** "Total CBD content" means the sum of the amount of CBD and 87.7 percent of the detectable amount of CBDA present in the product or plant material.

Subp. 45. **Total THC content.** "Total THC content" means the sum of the amount of THC and 87.7 percent of the detectable amount of THCA present in the product or plant material.

Subp. 46. **Water activity.** "Water activity" or "a_w" means a measure of the free moisture in usable cannabis and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

4770.0400 MEDICAL CANNABIS MANUFACTURER; OPERATIONS.

[For text of subpart 1, see Minnesota Rules]

Subp. 2. **Prohibited activities.**

[For text of item A, see Minnesota Rules]

B. A medical cannabis manufacturer and its employees, agents, or owners may not:

(1) cultivate, produce, or manufacture medical cannabis in any location except in those areas designated for those activities in the registration agreement;

(2) sell~~, deliver, transport,~~ or distribute medical cannabis or medical cannabis products from any location except its ~~manufacturing facility or its~~ distribution ~~facility~~ facilities;

[For text of subitem (3), see Minnesota Rules]

(4) sell or distribute medical cannabis to any person other than a registered:

[For text of units (a) to (c), see Minnesota Rules]

(5) deliver or transport medical cannabis to any location except ~~its~~ the manufacturer's production facility or distribution facilities ~~and~~, a waste-to-energy facility, another manufacturer's distribution facilities, a testing laboratory approved by the commissioner, and a laboratory selected by the commissioner to conduct audit testing under part 4770.3035;

[For text of subitems (6) and (7), see Minnesota Rules]

[For text of subparts 3 and 4, see Minnesota Rules]

4770.0850 PACKAGING AND LABELING.

[For text of subpart 1, see Minnesota Rules]

Subp. 2. **Medical cannabis ~~trade~~ brand names.** The medical cannabis manufacturer's medical cannabis ~~trade~~ brand names must comply with the following standards and are subject to approval by the commissioner:

[For text of items A and B, see Minnesota Rules]

C. any name that is identical to, or confusingly similar to, the name of an unlawful product or substance is prohibited; ~~and~~

D. any name that contains language that suggests using medical cannabis for recreational purposes or for a condition other than a qualifying medical condition is prohibited.~~;~~;

E. any name that is likely to be attractive to children; and

F. a brand name for dried raw cannabis may include the use of strain names. Brand names that include strain names that are likely to appeal to children may only be published or advertised on the manufacturer's website and in its distribution facilities.

[For text of subpart 3, see Minnesota Rules]

Subp. 4. **Supplemental label information.**

A. A manufacturer must include a supplemental label that contains information about each pesticide, including the manufacturer's name and brand name of the pesticide, that was applied to the cannabis plant or growth medium prior to or after harvest.

B. A manufacturer may include additional information, including:

(1) cannabis strain name(s) of the finished good;

(2) the results of terpene profile testing under part 4770.3032 and the date of testing;

(3) testing laboratory certificates of analysis for safety and potency;

(4) a warning to avoid operating a motor vehicle if impaired by medical cannabis;

(5) labeling information translated into another language; and

(6) other information approved by the commissioner.

C. The manufacturer may also provide the additional information required or permitted by this subpart on a product-specific page on the manufacturer's website, or through written material made available in its distribution facilities.

4770.1100 TRANSPORTATION OF MEDICAL CANNABIS.

Subpart 1. **Transportation of medical cannabis and plant material; when authorized.**

A. A medical cannabis manufacturer is authorized to transport medical cannabis:

(1) from its manufacturing facility to its distribution facilities;

(2) between its distribution facilities;

(3) from its manufacturing facility to a distribution facility operated by another manufacturer;

~~(2)~~ (4) from its manufacturing facility to a testing laboratory for testing; ~~and~~

(5) from a testing laboratory to its manufacturing facility or to a waste-to-energy facility;

(6) from its manufacturing facility or distribution facility to a laboratory selected by the commissioner to conduct audit testing under part 4770.3035; and

~~(3)~~ (7) from its manufacturing facility or distribution facility to a waste-to-energy facility.

B. A medical cannabis manufacturer is authorized to transport plant material waste:

[For text of subitems (1) and (2), see Minnesota Rules]

Subp. 2. **Transporting medical cannabis.**

A. A medical cannabis manufacturer must use a manifest system, approved by the commissioner, to track shipping of medical cannabis. The manifest system must include a chain of custody that records:

[For text of subitem (1), see Minnesota Rules]

(2) the weight, measure, or numerical count and description of each individual package that is part of the shipment, and the total number of individual packages;

[For text of subitems (3) to (6), see Minnesota Rules]

[For text of items B to E, see Minnesota Rules]

Subp. 3. **Transportation of medical cannabis; vehicle requirements.**

A. A manufacturer must ensure that:

(1) all medical cannabis transported on public roadways is:

(a) packaged in tamper-evident, bulk containers;

(b) transported so it is not visible or recognizable from outside the vehicle; ~~and~~

(c) transported in a vehicle that does not bear any markings to indicate that the vehicle contains cannabis or bears the name or logo of the manufacturer~~.~~; and

(d) kept in a compartment of a transporting vehicle that maintains appropriate temperatures and conditions that will protect plant material and medical cannabis against physical, chemical, and microbial contamination or deterioration.

B. Manufacturer employees who are transporting medical cannabis, plant waste, or medical cannabis waste on public roadways must:

(1) travel directly to the ~~distribution facility~~ destination listed on the transportation manifest; ~~and~~

(2) document refueling and all other stops in transit, including:

[For text of units (a) to (c), see Minnesota Rules]

(d) all activities of employees exiting the vehicle~~.~~; and

(3) not wear manufacturer-branded clothing or clothing that identifies the employee as an employee of the manufacturer.

[For text of items C to H, see Minnesota Rules]

4770.1700 MEDICAL CANNABIS MANUFACTURER; PRODUCTION REQUIREMENTS.

Subpart 1. **Cultivation and processing; generally.**

[For text of items A to F, see Minnesota Rules]

G. The manufacturer must maintain a record at the facility of all crop inputs for at least five years. The record must include the following:

[For text of subitems (1) and (2), see Minnesota Rules]

(3) the name and description of the crop input that was applied, including the chemical name, product name, and manufacturer, where applicable;

[For text of subitem (4), see Minnesota Rules]

(5) either the amount or concentration of crop input, or both, that was applied; ~~and~~

(6) a copy of the label of the crop input applied~~.~~; and

(7) the vendor or other origin of the crop input.

[For text of items H to J, see Minnesota Rules]

Subp. 1a. **Crop inputs used in cultivation of dried raw cannabis.**

A. A manufacturer cultivating plants intended to become dried raw cannabis must follow practices and procedures that minimize the risk of chemical contamination or adulteration of the medical cannabis.

B. A manufacturer may only apply a pesticide in the cultivation of medical cannabis if the pesticide has been:

(1) deemed to be minimum risk by the United States Environmental Protection Agency in accordance with the Code of Federal Regulations, title 40, section 152.25(f), and exempted from United States Code, title 7, section 136 et seq., the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the pesticide's label does not exclude its use on a genus cannabis plant;

(2) registered with the United States Environmental Protection Agency under section 3 of FIFRA, United States Code, title 7, section 136 et seq., and is labeled for use on medical cannabis or cannabis used for human consumption; or

(3) registered with the United States Environmental Protection Agency under section 3 of FIFRA, United States Code, title 7, section 136 et seq., and:

(a) the active ingredient found in the pesticide is either exempt from the tolerance requirements in Code of Federal Regulations, title 40, part 180, subpart D, or does not require an exemption from the tolerance requirement in Code of Federal Regulations, title 40, part 180, subpart E;

(b) the pesticide product label does not prohibit use within an enclosed structure for the site of application;

(c) the pesticide product label expressly has directions for use on unspecified crops or plants intended for human consumption; and

(d) the pesticide product is used in accordance with all applicable instructions, restrictions, and requirements on the product label.

B. A manufacturer may use rooting hormones or cloning gels only during the propagation phase of the plant life cycle.

C. A manufacturer must store all crop input stocks in their original containers with their original labels intact. The manufacturer must ensure that packaged fertilizers and containers of diluted or prepared fertilizer remain labeled with information as required in Minnesota Statutes, section 18C.215, at all times.

D. The manufacturer must apply, store, and dispose of crop inputs, rinsate, and containers according to label instructions and all other applicable laws and regulations.

E. If an audit sample tested under part 4770.3035 shows the presence of a crop input not permitted under this subpart, the batch and any finished good produced from the batch are adulterated and must be disposed of as medical cannabis waste under part 4770.1200, subpart 2. The use of pesticides not permitted under this part is presumptively classified as a serious violation under Minnesota Statutes, sections 144.989 to 144.993.

Subp. 2. **Production of medical cannabis.**

[For text of items A and B, see Minnesota Rules]

C. A manufacturer must ~~refrigerate perishable forms of medical cannabis~~ maintain appropriate temperatures and conditions that will protect plant material and medical cannabis against physical, chemical, and microbial contamination or deterioration of the product or its container.

[For text of item D, see Minnesota Rules]

E. Prior to distributing new finished goods to customers, a manufacturer must obtain the commissioner's approval. The commissioner shall:

(1) for each manufacturer, maintain a registered finished goods list containing packaged product information; and

(2) update the list as needed.

F. The manufacturer must submit a definition of each finished good to the commissioner to include in the registered finished goods list before a batch sample may be tested.

G. Pre-rolls must not contain more than 1.0 gram of dried raw cannabis each.

[For text of subparts 3 and 4, see Minnesota Rules]

4770.1750 MEDICAL CANNABIS DISTRIBUTION.

Subpart 1. **Distribution; identity verification.** A registered patient, designated caregiver, or the registered patient's parent or legal guardian, if the parent or legal guardian will be acting as a caregiver, must present a government-issued photo identification at the distribution site. Distribution site staff must verify the identity of the person and the patient's enrollment in the registry. In the case of a distribution that includes dried raw cannabis, the manufacturer must verify the age of the person and the age of the patient if someone other than the patient is making the transaction according to part 4770.1760.

Subp. 2. **Distribution; consultation.**

A. ~~The~~ If required under Minnesota Statutes, section 152.29, subdivision 3, paragraph (c), clause (4), a pharmacist employed by a manufacturer to distribute medical cannabis must consult with the registered patient, designated caregiver, or the registered patient's parent or legal guardian, if the parent or legal guardian will be acting as a caregiver, before distributing medical cannabis to the recipient. The consultation must include:

~~A.~~ (1) a review of patient information in the medical cannabis registry;

~~B.~~ (2) an assessment of the perceived effectiveness of medical cannabis in treating the condition or symptoms of the condition;

~~C.~~ (3) a review of current medications the patient is taking, including the formulation and current dosage of medical cannabis; and

~~D.~~ (4) a review of any changes in the patient's medical condition.

B. To determine whether a consultation must be held under Minnesota Statutes, section 152.29, subdivision 3, paragraph (c), clause (4), dried raw cannabis finished goods listed in a chemical composition range may be treated as other dried raw cannabis finished goods listed in that range.

C. A dried raw cannabis finished good is classified into one of three chemical composition ranges as follows:

(1) "High THC" if it has a total THC percentage greater than 15 percent;

(2) "Mixed" if it has a total THC percentage between five percent and 15 percent; or

(3) "Low THC" if it has a total THC percentage less than five percent.

D. A pharmacist may consult with a patient or caregiver regardless of whether a consultation is required under Minnesota Statutes, section 152.29, subdivision 3, paragraph (c), clause (4).

Subp. 3. **Distribution; dosage calculation.** After completing the consultation, the pharmacist will determine a recommended daily dosage and calculate an amount equal to a ~~30-day~~ 90-day supply at maximum recommended dosage. If a 90-day supply of dried raw cannabis exceeds 450 grams, the approving pharmacist must file a written justification of the calculation with the commissioner.

Subp. 4. **Purchasing limits.** A registered qualifying patient, registered designated caregiver, or a patient's registered parent or registered legal guardian may purchase medical cannabis in quantities less than or equal to the patient's 30-day supply determined under subpart 3 from any Minnesota distribution site at any time. The total quantity of medical cannabis purchased for a patient in a 23-day period must not exceed the patient's 30-day supply. A manufacturer must not distribute more than 450 grams of dried raw cannabis per visit to any person.

Subp. 5. **Dried raw cannabis display sample jars.**

A. In a distribution facility, a manufacturer may have dried raw cannabis packaged in a sample jar protected by a plastic or metal mesh screen to allow a patient or the patient's registered caregiver age 21 and older, to see and smell the product before purchase. A display sample jar must:

(1) not contain more than two grams of dried raw cannabis;

(2) be locked or sealed and tamper proof to prevent any person at the distribution facility from touching the dried raw cannabis; and

(3) have a plastic or metal mesh screen that is sealed onto the container and is free of rips, tears, or holes greater than two millimeters in diameter.

B. The display sample jar and the dried raw cannabis within may not be distributed to a patient and must be returned to the manufacturer's production facility where the cannabis must be disposed of as plant waste.

C. A jar used to contain display samples must be cleaned and disinfected before reuse.

D. All display sample jars must be labeled with:

(1) the manufacturer's name and logo;

(2) the medical cannabis brand name, including strain name if applicable;

(3) the unique identifier number generated by the track and trace system; and

(4) the weight of the product in ounces and grams or volume as applicable.

E. Outgoing and return samples and display sample jars are subject to the transportation requirements in part 4770.1100.

F. Dried raw cannabis used in sample jars must be accounted for in the manufacturer's inventory tracing under part 4770.1800. Dried raw cannabis used in sample jars must not be distributed for patients and must be disposed of as medical cannabis waste under part 4770.1200, subpart 2, item A.

4770.1760 DISTRIBUTION OF DRIED RAW CANNABIS; AGE VERIFICATION.

Subpart 1. **Sales only to those age 21 or older.** A manufacturer shall distribute dried raw cannabis only to persons age 21 or older and as part of a pharmacist-approved transaction.

Subp. 2. **Attainment of age.** With respect to purchasing, possessing, consuming, and selling dried raw cannabis, a person is not 21 years of age until 8:00 a.m. on the day of that person's twenty-first birthday.

Subp. 3. **Proof of age; defense.**

A. Proof of age for purchasing dried raw cannabis may be established only by:

(1) a valid driver's license or identification card issued by Minnesota, another state, or a province of Canada, and including the photograph and date of birth of the licensed person;

(2) a valid military identification card issued by the United States Department of Defense;

(3) a valid Tribal identification card issued by a federally recognized Minnesota Indian Tribe;

(4) a valid passport issued by the United States Department of State;

(5) a valid instructional permit issued under Minnesota Statutes, section 171.05, to a person of legal age to purchase alcohol which includes a photograph and the date of birth of the person issued the permit; or

(6) in the case of a foreign national, a valid passport.

B. In an administrative enforcement action based on this part, the manufacturer may provide evidence that it reasonably and in good faith relied upon representations of proof of age authorized in item A in selling, dispensing, or distributing dried raw cannabis for an enrolled patient.

4770.1800 INVENTORY.

[For text of subparts 1 and 2, see Minnesota Rules]

Subp. 3. ~~**Initial**~~ **Real-time inventory.** A medical cannabis manufacturer must maintain a real-time record of its inventory of plant material and medical cannabis to include:

A. the date and time of the inventory;

B. a summary of inventory findings~~:~~, including:

(1) the weight of cannabis seeds by type, strain, and cultivar;

(2) the total count of plants, whether in the flowering, vegetative, or clone phase of growth and organized by room in which the plants are grown;

(3) the batch number, weight or unit count, and strain name associated with each batch at the production facility that has been prepared for testing or is ready for transport to a distribution facility;

(4) the total number of plants that have been harvested but are not yet associated with a batch and every unique plant identifier;

(5) the amount of acquired industrial hemp; and

(6) the amount of medical cannabis, either by weight or units, sold since previous inventory, and listed by product name and registry identifier;

[For text of items C and D, see Minnesota Rules]

Subp. 4. **Waste inventory.** The medical cannabis manufacturer must maintain a real-time record of its inventory of all medical cannabis waste, including damaged, defective, expired, contaminated, recalled, or returned medical cannabis for disposal, and plant material waste for disposal.

Subp. 5. **Reconciliation.** At the close of business each day, a medical cannabis manufacturer must reconcile by conducting a physical inventory of all:

A. plant material at the manufacturing facility and in transit; and

B. medical cannabis at the manufacturing facility, each distribution facility, and in transit.

[For text of subpart 6, see Minnesota Rules]

Subp. 7. **Discrepancies.** If discrepancies are discovered outside of loss standard to the industry due to moisture loss and handling, the manufacturer must investigate the discrepancy and must submit a report of its investigation to the commissioner within seven days. If a discrepancy is due to suspected criminal activity, the manufacturer must notify the commissioner and appropriate law enforcement agencies in writing within 24 hours.

4770.1850 RECALL PROCEDURES.

A. Each manufacturer must establish a procedure for recalling medical cannabis that has a reasonable probability of causing an unexpected or harmful response in a patient

population, despite appropriate use, that outweighs the potential benefit of the medication. This procedure must include:

~~A.~~ (1) factors that make a recall necessary;

~~B.~~ (2) manufacturer's personnel who are responsible for overseeing the recall; and

~~C.~~ (3) how to notify affected parties of a recall.

B. The commissioner may order a manufacturer to undertake a recall of a dried raw cannabis finished good. The commissioner's order must be based on a reasonable suspicion that the finished good presents a risk of causing a serious adverse incident. The commissioner must order the recall of a dried raw cannabis finished good if testing under part 4770.3035 indicates the presence of residues from a crop input prohibited under part 4770.1700 are present in the finished good. A manufacturer must comply and cooperate with any recalls ordered by the commissioner.

4770.1900 MEDICAL CANNABIS LABORATORY APPROVAL.

[For text of subparts 1 to 3, see Minnesota Rules]

Subp. 4. **Commissioner's approved medical cannabis product types.** The commissioner's approved product types include:

[For text of items A and B, see Minnesota Rules]

C. vaporized delivery method using liquid or oil~~, but not dried leaves or plant form~~; ~~and~~

D. dried raw cannabis intended to be used or consumed by combustion; and

~~D.~~ E. any other method~~, excluding smoking,~~ approved by the commissioner under Minnesota Statutes, section 152.27, subdivision 2, paragraph (b).

[For text of subpart 5, see Minnesota Rules]

4770.2000 MEDICAL CANNABIS LABORATORY APPROVAL; APPLICATION AND APPROVAL.

Subpart 1. **Application requirements.**

[For text of items A to C, see Minnesota Rules]

D. The following items are required and must be submitted to the commissioner before December 31, ~~2016~~ 2022:

(1) a copy of the lab's ISO/IEC ~~17025:2005~~ 17025:2017 Certificate and Scope of Accreditation; and

[For text of subitem (2), see Minnesota Rules]

[For text of subparts 2 and 3, see Minnesota Rules]

4770.3002 TESTING SAMPLES; COLLECTION; HANDLING; DISPOSAL.

A. A batch sample of cured cannabis flower from each batch of dried raw cannabis must be sent to a testing laboratory for testing. The batch sample must pass all required tests before the dried raw cannabis may be packaged for distribution to patients.

B. The manufacturer must schedule with a testing laboratory with which it has a contract to test medical cannabis to collect the batch sample at least 48 hours before the batch sample is collected. An employee of the manufacturer must be present to observe the sample collection. The testing laboratory employee must minimize potential contamination when collecting a batch sample, such as using sterile gloves and equipment.

C. A batch sample must be composed of 15 grams of intact cannabis flowers from a single batch of dried raw cannabis, taken from different bulk containers, if applicable, and from different areas within the bulk container.

D. The testing laboratory employee or contractor collecting the batch sample must certify the batch number from which the sample is collected and the date and time of collection and document the bulk container or containers and the general locations within the containers from which the sample is collected. The manufacturer employee who observed the collection must certify that the batch sample collected is representative of the batch and that the collection followed procedures to minimize contamination of the batch sample.

E. Before the batch sample is transported to a testing laboratory, the batch sample must be placed in a transport container with a tamper-evident seal affixed by the testing laboratory employee or contractor who collected the sample.

F. The manufacturer must transport the batch sample to a testing laboratory for testing within 48 hours of the sample collection. The testing laboratory must certify upon receipt that the tamper-evident seal is intact and that the sample was collected less than 48 hours earlier. If the tamper-evident seal is broken or if the collection occurred more than 48 hours earlier, the testing laboratory must not accept the batch sample for testing.

G. The testing laboratory must grind the batch sample to create a representative composite batch sample for testing. The testing laboratory may also use a paddle blender on all or part of the batch sample to produce a homogenous composite batch sample. All required testing must be performed on the composite batch sample.

H. Within 30 calendar days after testing of a batch sample is complete, the manufacturer must retrieve from the testing laboratory the analyzed batch sample and the waste containing medical cannabis. The manufacturer must transport the waste material either to the manufacturer's production facility where it must be quarantined before disposal or directly to a waste-to-energy disposal site.

4770.3010 COMPLIANCE TESTING REQUIREMENTS FOR DRIED RAW CANNABIS.

A. A manufacturing facility must have each batch of dried raw cannabis tested for:

(1) water activity and moisture content in accordance with part 4770.3011;

(2) microbiological contaminants and mycotoxins in accordance with part 4770.3021;

(3) heavy metals in accordance with part 4770.3022; and

(4) cannabinoid potency in accordance with part 4770.3030.

B. More than one testing laboratory may conduct the required tests on a batch but each required test must only be conducted by a single laboratory.

4770.3011 WATER ACTIVITY AND MOISTURE CONTENT TESTING OF DRIED RAW CANNABIS.

Subpart 1. **Requirement.** Before being packaged, each batch of dried raw cannabis must be tested for:

A. water activity; and

B. moisture content.

Subp. 2. **Standards.** A batch of dried raw cannabis sample fails if it has:

A. a water activity rate of more than 0.65 a_w; or

B. a moisture content of more than 15 percent.

Subp. 3. **Remediation of failed samples.** If the batch of dried raw cannabis samples do not pass testing standards for water activity and moisture content, the batch from which the sample was taken may:

A. be used to make a medical cannabis concentrate which must comply with testing requirements; or

B. continue to dry or cure.

Subp. 4. **Requirement.** A batch of dried raw cannabis sample must pass water activity and moisture content testing before other required tests may be performed on that sample. If a batch sample fails either water activity or moisture content testing, the testing laboratory must not conduct additional tests on that batch sample and must issue a certificate of analysis for the batch sample indicating the result and "NT" for other tests scheduled.

4770.3020 SAFETY TESTING PROCEDURES.

A. A batch of dried raw cannabis sample must pass safety testing at a testing laboratory before any finished goods produced from that batch are transported to a distribution facility.

B. A manufacturer must submit a minimum of 15 grams of dried raw cannabis to a testing laboratory for the full spectrum of safety testing. The testing laboratory must notify in writing both the manufacturer and the commissioner if the testing laboratory requires more than 15 grams of dried raw cannabis to conduct the testing.

C. A batch of dried raw cannabis sample must pass both microbiological and mycotoxins testing under part 4770.3021 and heavy metals testing under part 4770.3022 to pass safety testing.

4770.3021 MICROBIOLOGICAL AND MYCOTOXINS TESTING OF DRIED RAW CANNABIS.

Subpart 1. **Testing required.** Before being packaged, a representative sample from each batch of dried raw cannabis must be tested for microbiological contaminants and mycotoxins using an AOAC-approved technology using appropriate aseptic techniques.

Subp. 2. **Microbiological contaminant tests.** A dried raw cannabis sample passes the microbiological contaminant test if it meets the following standards for microbial and fungal limits in colony forming units per gram (CFU/g):

	Standard
Total viable aerobic bacteria	$< 10^5$ CFU/g
Total yeast and mold	$< 10^4$ CFU/g
Total coliforms	$< 10^3$ CFU/g
Bile-tolerant gram-negative bacteria	$< 10^3$ CFU/g
Escherichia coli and salmonella species	Not detected in one gram

Subp. 3. **Mycotoxin tests.** For purposes of the mycotoxin test, a dried raw cannabis sample passes if:

A. the total of aflatoxin B1, B2, G1, and G2 is less than 20 micrograms per kilogram of substance;

B. aflatoxin B1 does not exceed 5 micrograms per kilogram of substance; and

C. ochratoxin A is less than 20 micrograms per kilogram of substance.

Subp. 4. **Remediation.** A manufacturer must comply with the requirements in this subpart when a sample fails to meet the standards for microbiological contaminant or mycotoxin testing.

A. If a sample from a batch of dried raw cannabis fails microbiological contaminant or mycotoxin testing, the manufacturer may attempt to remediate the batch one time and resubmit a batch sample for testing. If a batch of dried raw cannabis fails microbiological contaminant or mycotoxin testing after remediation, the manufacturer may:

(1) use the batch to make a medical cannabis concentrate if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon-based solvent

or a carbon dioxide closed loop system, or the processing method selectively removes the mycotoxins from the batch; or

(2) dispose of the batch as medical cannabis waste under part 4770.1200, subpart 2, item A.

B. A batch that is remediated in accordance with this subpart must be resampled and tested in accordance with this chapter.

4770.3022 HEAVY METALS TESTING OF DRIED RAW CANNABIS.

Subpart 1. **Requirement.** Before being packaged, a representative sample from each batch of dried raw cannabis must be tested for the presence of heavy metals.

Subp. 2. **Standards.** A batch fails heavy metals testing if the presence of one of the following metals is above the following listed limit:

	Parts per Million (ppm)
Inorganic arsenic	0.4
Cadmium	0.3
Lead	1.0
Mercury	0.2

Subp. 3. **Remediation.** A manufacturer must comply with the following requirements when a sample fails to meet the standards for heavy metals testing.

A. A batch of dried raw cannabis that fails heavy metals testing may be remediated using a processing method that effectively removes the heavy metals from the batch. If a batch of dried raw cannabis fails heavy metals testing after remediation, the manufacturer must dispose of the batch as medical cannabis waste under part 4770.1200, subpart 2, item A.

B. A batch that is remediated in accordance with this subpart must be sampled and tested in accordance with this chapter.

4770.3030 POTENCY TESTING OF DRIED RAW CANNABIS.

Subpart 1. **Cannabinoid content.**

A. Before being packaged, a representative sample from each batch of dried raw cannabis must be tested to establish the concentration of cannabinoid analytes, reported as the percentage content by weight for:

(1) Delta-9-tetrahydrocannabinol (THC);

(2) Delta-9-tetrahydrocannabinolic acid (THCA);

(3) Cannabidiol (CBD); and

(4) Cannabidiolic acid (CBDA); and

(5) any other cannabinoid determined by the commissioner.

B. The commissioner must maintain a list on the Office of Medical Cannabis website (http://mn.gov/medicalcannabis) of all cannabinoids required to be analyzed by the testing laboratory. In addition to publication on the Office of Medical Cannabis website, updates to the list must be communicated by e-mail to each registered manufacturer and to each approved laboratory.

C. In addition, the testing laboratory must calculate and report the total THC content and total CBD content:

(1) Total THC content is calculated:

Total THC = %THC + (%THCA x 0.877).

(2) Total CBD content is calculated:

Total CBD = %CBD + (%CBDA x 0.877).

Subp. 2. **Triple preparation; sample potency.**

A. The testing laboratory must use a triple preparation to determine the potency of the sample. If multiple preparations are used, the reported potency must be the mean value of the results. The relative standard deviation between the tested samples must be ten percent or less.

B. The testing laboratory must notify in writing both the manufacturer and the commissioner if it requires a sample of more than two grams of dried raw cannabis to conduct the testing before the testing begins.

4770.3032 TERPENE ANALYSIS.

A. A manufacturer may request a testing laboratory to analyze at minimum 0.5 grams of the batch sample to determine the terpenoid profile of the sample. A list of terpenes that may be tested will be published on the Office of Medical Cannabis website (http://mn.gov/medicalcannabis).

B. The testing laboratory must report the result of the terpenoid testing on the certificate of analysis both as a percentage and in either milligrams per gram (mg/g) if by weight or milligrams per milliliter (mg/mL) if by volume.

C. A manufacturer may include terpenoid profile information on the label of a container holding dried raw cannabis only when a terpene analysis is performed under this part.

4770.3035 AUDIT TESTING FOR PROHIBITED PESTICIDES AND COMPLIANCE.

A. The commissioner may require audit testing of plant materials, dried raw cannabis batch samples, or dried raw cannabis finished goods to ensure compliance with this chapter and any other applicable law, and to protect the public health and safety. The commissioner may either collect or require the manufacturer to submit up to five ten-gram

samples per month for audit testing. The manufacturer must transport the audit sample or samples to a laboratory selected by the commissioner for testing.

B. The audit testing may test for:

(1) pesticides and other crop inputs;

(2) heavy metals;

(3) microbiological contaminants and microtoxins;

(4) solvents; and

(5) adulterants, additives, or other contaminants that may pose a risk to public health and safety or that are prohibited by law.

C. A laboratory conducting audit testing under item A must report its findings to the commissioner in writing.

D. If an audit test finds the presence of a prohibited pesticide in a sample, the manufacturer must send another sample from the affected batch to a testing laboratory to conduct a quantitative analysis for the specific analytes indicated in the audit sample report.

E. Within 90 calendar days after the audit test report is complete, the manufacturer must retrieve from the laboratory the remaining sample material and waste containing medical cannabis. The manufacturer must transport the waste material either to the manufacturer's production facility where it must be quarantined before disposal or directly to a waste-to-energy disposal site.

F. The manufacturer must pay for all testing done under this part.

4770.3040 STABILITY AND DEGRADATION TESTING OF DRIED RAW CANNABIS.

A. The manufacturer must provide the third-party testing laboratory with an adequate number of dried raw cannabis samples in their final packaged form to create

composite samples at the four distinct timepoints listed in item B. The stability samples must be stored according to label instructions.

B. The testing laboratory must test the potency of the stability samples at zero, three, six, and 12 month intervals to monitor changes in total THC content and total CBD content.

C. If the value at any of the subsequent timepoints changes by ten percent or more compared to T = 0 when tested in triplicate, the cured flower will be assigned an expiration period based upon the time it dropped below ten percent of T = 0.

D. Until data has been collected establishing evidence-based expiration dates, a dried raw cannabis product will have a six-month expiration date.

E. The testing laboratory must store each stability sample according to the product's label instructions. If there are no applicable label instructions, then the sample must be stored at room temperature and not in direct sunlight.