TITLE 238 NEBRASKA MEDICAL CANNABIS COMMISSION

CHAPTER 1 REGISTERED CANNABIS ESTABLISHMENTS

- **<u>001.</u>** SCOPE AND AUTHORITY. These regulations implement the Nebraska Medical Cannabis Regulation Act as authorized by Nebraska Revised Statute (Neb. Rev. Stat.) § 71-24,111.
- **<u>002.</u> <u>DEFINITIONS.</u>** The definitions found in Neb. Rev. Stat. § 71-24,104 and § 71-24,107 and the following definitions apply:
 - <u>002.01</u> <u>ADULTERANT.</u> Adulterant means any poisonous or deleterious substance in a quantity that may be injurious to health, including: pesticides, heavy metals, solvents, microbial life, toxins, foreign matter, or artificially derived cannabinoids.
 - <u>002.02</u> <u>ADVERSE EVENT.</u> Adverse event means an unfavorable or harmful medical occurrence, such as an abnormal sign, symptom, or disease.
 - <u>002.03</u> <u>ANALYTE</u>. Analyte means a substance or chemical component that is undergoing analysis.
 - <u>002.04</u> <u>ARTIFICALLY DERIVED CANNABINOID.</u> Artificially derived cannabinoid means a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from the cannabis plant. Artificially derived cannabinoid does not include:
 - (A) A naturally occurring chemical substance that is separated from the cannabis plant by a chemical or mechanical extraction process; or
 - (B) A cannabinoid that is produced by decarboxylation from a naturally occurring cannabinoid acid without the use of a chemical catalyst.

002.05 BATCH. Batch means a quantity of:

- (A) Medical cannabis concentrate produced on a particular date and time, following clean up until the next clean up during which the same lots of medical cannabis are used;
- (B) Medical cannabis product produced on a particular date and time, following clean up until the next clean up during which medical cannabis concentrate is used; or
- (C) Cannabis flower from a single strain and growing cycle packaged on a particular date and time, following clean up until the next clean up during which lots of medical cannabis are being used.
- <u>002.06</u> <u>CANNABINOID.</u> Cannabinoid means any naturally occurring derivative of cannabigerolic acid (CAS 25555-57-1) or any chemical compound that is both structurally and chemically similar to a derivative of cannabigerolic acid.
- <u>002.07 CANNABINOID CONCENTRATE.</u> Cannabinoid concentrate means the product of any chemical or physical process applied to naturally occurring biomass that concentrates or isolates the cannabinoids contained in the biomass or any amount of a natural or artificially derived cannabinoid.
- <u>002.08</u> <u>CANNABIS DERIVATIVE PRODUCT.</u> Cannabis derivative product means a medical cannabis product made using cannabis concentrate.

- <u>002.09 CERTIFICATE OF ANALYSIS.</u> Certificate of analysis means a document produced by a testing laboratory listing the quantities of the various analytes for the performed testing. It must also include the name of the testing laboratory, the laboratory's address, a representative for the laboratory, contact information for the laboratory's representative, the laboratory's applicable accreditations under the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC).
- <u>002.10 CLONE.</u> Clone means a non-flowering plant cut from a mother plant that is capable of developing into a new plant and has shown no signs of flowering.
- 002.11 COVERED LOCATION. Covered location means any school, business operating under a license issued pursuant to the Nebraska Child Care Licensing Act Neb. Rev. Stat. § 71-1908 to § 71-1923.03, church, hospital, or mental health substance use treatment center as defined by Neb. Rev. Stat. § 71-423.
- <u>002.12</u> <u>CULTIVATOR.</u> Cultivator means a registered establishment licensed to cultivate and process cannabis plants for sale and transport to dispensaries, product manufacturers, and to other cultivators, but cannot transfer cannabis plants or cannabis products to qualified patients or caregivers.
- <u>002.13 DELTA-9-TETRAHYDROCANNABINOL.</u> Delta-9-tetrahydrocannabinol (delta-9-THC) means the cannabinoid identified as CAS #1972-08-03, the primary psychotropic cannabinoid in cannabis.
- <u>002.14</u> <u>DIRECTORY.</u> Directory means the Recommending Health Care Practitioner Directory established by this chapter.
- <u>002.15</u> <u>DISPENSARY.</u> Dispensary means a registered establishment licensed to possess, sell or transfer medical cannabis to qualified patients or caregivers.
- <u>002.16 FINAL PRODUCT.</u> Final product means a reasonably homogenous medical cannabis product created using the same standard operating procedures and the same formulation in its final packaged form, or for nebulizer in the sealed cartridge.
- <u>002.07 FLOWERING PLANT.</u> Flowering plant means a medical cannabis plant from the time it exhibits the first signs of sexual maturity through harvest.
- <u>002.08</u> <u>FOREIGN MATTER.</u> Foreign matter means any matter that is present in a medical cannabis lot that is not a part of the cannabis plant or any matter that is present in medical cannabis or a medical cannabis product that is not listed as an ingredient, including seeds.
- <u>002.09</u> <u>IMMATURE PLANT.</u> Immature plant means a nonflowering cannabis plant that has not demonstrated signs of flowering.
- <u>002.10</u> <u>LICENSE.</u> License means a registration granted by the Nebraska Medical Cannabis Commission in accordance with the Nebraska Medical Cannabis Regulation Act.
- <u>002.11</u> <u>LOCAL GOVERNMENT.</u> Local government means a village, town, city, or county.
- 002.12 LOT. Lot means the quantity of:

- (A) Flower from a single strain of cannabis and growing cycle produced on a particular date and time, following clean up until the next clean up during which the same materials are used; or
- (B) Trim, leaves, or other plant matter from cannabis produced on a particular date and time, following clean up until the next clean up.
- <u>002.13</u> <u>MEDICAL CANNABIS CULTIVATION BYPRODUCT.</u> Medical cannabis cultivation byproduct means any portion of a cannabis plant that is not intended to be sold as a medical cannabis product.
- <u>002.14</u> <u>MEDICAL CANNABIS WASTE.</u> Medical cannabis waste means medical cannabis that is unused, unwanted, damaged, defective, expired, or contaminated.
- <u>002.15 MOTHER PLANT.</u> Mother plant means a cannabis plant that is grown or maintained for the purpose of generating clones, and that will not be used to produce plant material for sale to a processor or dispensary.

002.16 PEST. Pest means:

- (A) Any insect, rodent, nematode, fungus, weed; or
- (B) Any other form of terrestrial or aquatic plant or animal life, virus, bacteria, or other microorganisms that are injurious to health or to the environment.

<u>002.17 PESTICIDE.</u> Pesticide means any:

- (A) Substance, herbicide, or mixture of substances, including a living organism, that is intended to prevent, destroy, control, repel, attract, or mitigate any insect, rodent, nematode, snail, slug, fungus, weed, or other forms of plant or animal life that are normally considered to be a pest;
- (B) Any substance, herbicide, or mixture of substances intended to be used as a plant regulator, defoliant, or desiccant; or
- (C) Any spray adjuvant, such as a wetting agent, spreading agent, deposit builder, adhesive, or emulsifying agent with deflocculating properties of its own, used with a pesticide to aid in the application or effect of a pesticide.
- <u>002.18</u> <u>PRODUCT MANUFACTURER.</u> Product Manufacturer means a registered establishment licensed to process cannabis, conduct extractions, and manufacture cannabis products for sale or transfer to dispensaries, but cannot sell or transfer cannabis plants or cannabis products to qualified patients or caregivers.

002.19 PRODUCTION BATCH. Production batch means:

- (A) Any amount of medical cannabis concentrate or nonliquid medical cannabis products, of the same category and produced using the same extraction methods, standard operating procedures, and an identical group of harvest batch of medical cannabis; or
- (B) Any amount of medical cannabis product of the same exact type produced using the same ingredients, standard operating procedures, and same production batch of medical cannabis concentrate or same harvest batch of medical cannabis.
- <u>002.20 SAMPLING TECHNICIAN.</u> Sampling technician means a person tasked with collecting a representative sample of medical cannabis, medical cannabis concentrate, or medical cannabis product from a registered cannabis establishment who is:
 - (A) An employee or agent of the Commission;

- (B) An employee of an independent cannabis laboratory that is approved by the Commission to perform sampling; or
- (C) A person authorized by the Commission to perform sampling.
- <u>002.21</u> <u>SEED-TO-SALE SYSTEM.</u> Seed-to-sale system means an electronic inventory tracking system utilized by a registered cannabis establishment to track inventory, any steps through the process of cultivating or manufacturing medical cannabis or medical cannabis products, transactions with other registered cannabis establishments, testing, and other required information for the purpose of reporting that information to the Commission in accordance with Nebraska law, rules, and regulations.
- <u>002.22</u> <u>STATE INVENTORY TRACKING SYSTEM.</u> State inventory tracking system means the required tracking system established by the Commission that accounts for medical cannabis from either the seed or immature plant stage until the medical cannabis or medical cannabis product is sold to a patient at a licensed dispensary, disposed of in accordance with these rules, or used in a research project by a medical cannabis research facility. The State's inventory tracking system accounts for the entire life span of medical cannabis and medical cannabis products, including any testing samples thereof and medical cannabis waste.
- <u>002.23</u> <u>THC ANALOG.</u> THC analog means a substance that is structurally or pharmacologically substantially similar to, or is represented as being similar to, Delta-9-tetrahydrocannabinol (delta-9-THC). THC analog does not include the following substances or the naturally occurring acid forms of the following substances:
 - (A) Cannabichromene (CBC), the cannabinoid identified as CAS# 20675-51-8;
 - (B) Cannabicyclol (CBL), the cannabinoid identified as CAS# 21366-63-2;
 - (C) Cannabidiol (CBD), the cannabinoid identified as CAS# 13956-29-1;
 - (D) Cannabidivarol (CBDV), the cannabinoid identified as CAS# 24274-48-4;
 - (E) Cannabielsoin (CBE), the cannabinoid identified as CAS# 52025-76-0;
 - (F) Cannabigerol (CBG), the cannabinoid identified as CAS# 25654-31-3;
 - (G) Cannabigerovarin (CBGV), the cannabinoid identified as CAS# 55824-11-8;
 - (H) Cannabinol (CBN), the cannabinoid identified as CAS# 521-35-7;
 - (I) Cannabivarin (CBV), the cannabinoid identified as CAS# 33745-21-0; or
 - (J) Delta-9-tetrahydrocannabivarin (THCV), the cannabinoid identified as CAS# 31262-37-0.
- <u>002.24</u> <u>TOTAL CBD.</u> Total CBD means the sum of the determined amounts of Cannabidiol (CBD) and Cannabidiolic acid (CBDA).
- <u>002.25</u> <u>TOTAL.</u> Total THC means the sum of the determined amounts of Delta-9-tetrahydrocannabinol (delta-9-THC) and Delta-9-tetrahydrocannabinolic acid (delta-9-THCA) according to the formula: Total THC = delta-9-THC + (delta-9-THCA x 0.877).
- <u>002.26</u> <u>TRANSPORTER.</u> Transporter means a registered establishment licensed to transport medical cannabis, medical cannabis products, and medical cannabis accessories between medical cannabis licensees, provide logistical services for medical cannabis licensees, or store medical cannabis.
- <u>002.27 UNIT.</u> Unit means each individual portion of an individually packaged medical cannabis product.

<u>002.28</u> <u>UNKNOWN CANNABINOID.</u> Unknown cannabinoid means any component of a medical cannabis, medical cannabis concentrate, or medical cannabis product that a laboratory determines is likely to be a cannabinoid by comparison of physical properties, including molecular weight, retention time, and absorption spectra but is not included in Table 2 or Table 3.

<u>002.29 WATER ACTIVITY.</u> Water activity means a dimensionless measure of the water present in a substance that is available to microorganisms; calculated as the partial vapor pressure of water in the substance divided by the standard state partial vapor pressure of pure water at the same temperature.

<u>002.30</u> <u>WRITTEN ORDER.</u> Written order means a written description by a health care practitioner that includes the following:

- (A) The patient name;
- (B) The patient date of birth;
- (C) The patient address and contact information;
- (D) Information regarding the qualified patient's caregiver, if applicable;
- (E) The medical cannabis product being recommended;
- (F) The recommended dosage and potency;
- (G) The number of doses;
- (H) Directions for use;
- (I) The name, address, and professional license number of the recommending health care practitioner;
- (J) A statement that the recommending health care practitioner met with the qualified patient in-person at least once in the last twelve (12) months;
- (K) A statement attesting the qualified patient is not pregnant; and
- (L) The dispensary the qualified patient intends to utilize to fill the written order.

003. REGISTERED ESTABLISHMENT APPLICATION PROCESS.

<u>003.01 APPLICATION TIME PERIODS.</u> Applications for registered establishments will be accepted only during the time period published on the Commission's website. The time period may be extended by publication of a new deadline on the website.

<u>003.02</u> <u>COMPLETE APPLICATION.</u> Applications are considered complete if the application includes all information and documents required by this chapter.

<u>003.03 APPLICATION SUBMISSION.</u> Applications shall be submitted to the Commission by electronic submission to the electronic mail address on the Commission's webpage, by submission through an electronic application portal designated by the Commission, or by first-class mail to the mailing address on the Commission's webpage. If submitted by first-class mail, the application must be postmarked no later than the date of the application deadline. If submitted electronically, the application must be received by the Commission no later than 11:59 p.m. on the date of the application deadline.

003.03(A) APPLICATION RESTRICTIONS. An applicant may not:

- (i) Submit more than one application for the same license type during the same application time period; or
- (ii) Submit applications for more than one license type issued under this chapter during the same application time period.

<u>003.04</u> <u>LOTTERY.</u> In the event there are more applications than available licenses, the Commission will select applicants for available licenses by lottery.

<u>003.04(A)</u> <u>ENTRY INTO LOTTERY.</u> All applications submitted during an application time period will be entered into the lottery. Applications submitted after the application time period will be denied.

<u>003.04(B)</u> <u>APPLICATION IDENTIFICATION FOR LOTTERY.</u> Applications entered into the lottery will be assigned an application identifier by the Commission. The assigned identifiers will be transmitted to the entity conducting the lottery. Any entity or individual conducting the lottery will do so without reference to the identifies of the applicants, and will not be provided with any additional information about the applicant other than the assigned identifier.

<u>003.04(C)</u> <u>LOTTERY DRAWING.</u> Assigned identifiers will be randomly drawn and listed in the order drawn. If licenses are issued by judicial district, separate drawings will occur for each district.

<u>003.04(D)</u> <u>APPLICATION REVIEW.</u> After identifiers are drawn, the Commission will review the application corresponding to the selected identifier, beginning with the first identifier drawn, to determine if the application is complete and meets eligibility scoring requirements for licensure.

<u>003.04(E)</u> <u>ELIGIBILITY SCORING REQUIREMENTS.</u> Applications will be scored based on several core criteria, with primary emphasis placed on comprehensive business plans, financial stability, facility design, and operational readiness, collectively ensuring a solid foundation for sustainable operations. Applications with an average score of more than 70 points out of 100 points will be eligible for licensure.

<u>003.04(F)</u> <u>APPROVAL.</u> If an application being reviewed is determined by the Commission to meet all licensure eligibility requirements in this chapter, the license will be approved. An application may be denied as allowed by this chapter.

<u>003.04(G)</u> <u>AVAILABLE LICENSES.</u> Once an application is approved or denied the Commission will review the next application in the order drawn until the available licenses are issued. Once all available licenses are issued, the remaining applications entered into the lottery for that application time period will be denied for failure to be selected in that lottery.

<u>003.05</u> <u>LICENSURE WITHOUT LOTTERY.</u> In the event fewer applications are received in an application time period than there are available licenses, or for applications for licenses without a limit on the number of licenses to be issued, all complete applications will be reviewed by the Commission. Applications with an average score of more than 70 points out of 100 points will be eligible for licensure.

<u>003.06 ACCEPTANCE OF LICENSE</u>. All applicants approved for licensure will be given forty-eight (48) hours to confirm acceptance of the license in writing. Failure to timely accept the license may result in deactivation or revocation of the license and the license may be offered to the next eligible applicant in drawn order.

<u>003.07 NON-REFUNDABLE APPLICATION FEE.</u> If a fee is required for an application, the application fee once submitted is non-refundable regardless of whether a license is issued.

<u>003.08 LICENSE DURATION.</u> If a fee is required for an application or renewal, licenses are valid for a period of one year from the date of issuance. If a fee is not required for the application or renewal, licenses are valid for a period of six (6) months from the date of issuance.

004. DISPENSARY LICENSE APPLICATION.

<u>004.01</u> <u>VERTICAL LICENSING.</u> Vertical licensing is not permitted. An applicant may not possess more than one license type authorized by this chapter.

<u>004.02</u> <u>FINGER PRINTING.</u> An applicant for initial issuance of any license under this chapter shall also submit two legible sets of fingerprints to be furnished for every person included in the application to the Nebraska State Patrol for a criminal history record information check and fee for such record check payable to the patrol. The applicant shall authorize the release of the criminal history record information check to the Commission.

<u>004.03</u> <u>RESIDENCY REQUIREMENTS.</u> The following residency and citizenship requirements apply to any licensee applicant:

- (A) Must be majority owned by a United States citizen(s) who has been a resident(s) of Nebraska for no less than four years immediately preceding the application; and
- (B) Majority owned means more than fifty-one percent (51%) of the financial interests (other than a security interest, lien, or encumbrance) or more than fifty-one percent (51%) of the voting interests of an entity, including any parent and subsidiary entities.

004.04 REQUIRED INFORMATION. An application shall include the following:

- (A) The name and address of the applicant and if applicable, the applicant's officers, directors, or managers;
- (B) A statement that the applicant and the applicant's officers, directors, or managers satisfy the residency requirements provided in this chapter, and none have a disqualifying conviction;
- (C) The premises for which a license is desired, designating the premises by street and number, if practicable, or by such other description as to definitively locate the premises;
- (D) The name of the owner of the premises upon which the business licensed is to be operated;
- (E) A statement that the applicant is in compliance with any applicable state or local laws, regulations, or ordinances;
- (F) A statement that the applicant has paid all state and local taxes that are due, as well as any additional fees imposed by law;
- (G) A summary of the applicant's business experience and a business plan meeting the criteria set out in this chapter; and
- (H) Any additional requirements based on the type of license the applicant is applying for as set forth in this chapter.

<u>004.05</u> <u>BUSINESS PLAN REQUIREMENTS.</u> A business plan submitted by an applicant must include the following:

(A) Proof of financial capability to build, launch, and sustain the dispensary, including access to capital, a detailed budget, and funding sources;

- (B) Facility design and operational readiness, including compliance with all applicable state laws and regulations and a demonstration of readiness to commence operations;
- (C) Demonstration of how the applicant meets the residency requirements in this chapter;
- (D) Any experience in operating a business in a regulated industry;
- (E) Any experience in cannabis cultivation, cannabis manufacturing, or cannabis retail;
- (F) Leadership team qualifications; and
- (G) Financial projections for the next year.

<u>004.06</u> <u>FALSE STATEMENTS.</u> If any false statement is made in any part of the application the license may be denied or revoked.

004.07 PROHIBITED PERSONS. A license shall not be issued to or held by:

- (A) Any person who has been convicted of any felony or any controlled substance related offense within the preceding ten (10) years;
- (B) An entity if any of its officers, directors, or owners have been convicted of any felony or any controlled substance related offense within the preceding ten (10) years;
- (C) An entity if any of its officers, directors, or owners have had a license or permit suspended or revoked pursuant to these regulations;
- (D) A person under the age of majority;
- (E) Any state, county, municipality, or other political subdivision, any branch, department, agency, or subdivision of any of the foregoing, or any corporation or other body established by law to carry out any government function;
- (F) A health care practitioner who has issued one or more written recommendations or written orders in the preceding five years; or
- (G) A person who has had any citation, fine, sanction, injunction or court judgment levied against the person, or a business owned by the person, involving cannabis or cannabinoid related operations or sales.
- <u>004.08 LOCATION.</u> No dispensary license will be issued for any premises located within one thousand feet of any covered location. Except that this subsection shall not apply to any licensee operating an established registered cannabis establishment that was in operation prior to the covered location being established within one thousand feet of such establishment. One thousand feet will be measured in a straight line from the nearest property line of the covered location to the nearest perimeter wall of the licensed premises.
- <u>004.09</u> <u>LICENSEE RELOCATION.</u> A licensee shall not relocate a registered cannabis establishment from the place specified in the license.
- <u>004.10</u> <u>LICENSE TRANSFER.</u> Licenses are non-transferrable.
- 004.11 NUMBER OF LICENSES ALLOWED. No more than one (1) dispensary license shall be issued in any one district court judicial district as defined in Neb. Rev. Stat. § 24-301.02. If during any calendar year the Commission finds the number of licensed dispensaries in any district is not sufficient to meet the demand for medical cannabis or medical cannabis products, the Commission may grant an additional one (1) dispensary license in the identified district or districts during the following year.

005. CULTIVATOR LICENSE APPLICATION.

<u>005.01</u> <u>VERTICAL LICENSING.</u> Vertical licensing is not permitted. An applicant may not possess more than one license type authorized by this chapter.

<u>005.02</u> <u>FINGER PRINTING.</u> An applicant for initial issuance of any license under this Chapter shall also submit two legible sets of fingerprints to be furnished for every person included in the application to the Nebraska State Patrol for a criminal history record information check and fee for such record check payable to the patrol. The applicant shall authorize the release of the criminal history record information check to the Commission.

<u>005.03</u> <u>RESIDENCY REQUIREMENTS.</u> The following residency and citizenship requirements apply to any licensee applicant:

- (A) Must be majority owned by a United States citizen(s) who has been a resident(s) of Nebraska for no less than four years immediately preceding the application; and
- (B) Majority owned means more than fifty-one percent (51%) of the financial interests (other than a security interest, lien, or encumbrance) or more than fifty-one percent (51%) of the voting interests of an entity, including any parent and subsidiary entities.

<u>005.04</u> <u>REQUIRED INFORMATION.</u> An application shall include the following:

- (A) The name and address of the applicant and if applicable, the applicant's officers, directors, or managers;
- (B) A statement that the applicant and the applicant's officers, directors, or managers satisfy the residency requirements provided in this chapter, and none have a disqualifying conviction;
- (C) The premises for which a license is desired, designating the premises by street and number, if practicable, or by such other description as to definitively locate the premises and whether cultivation will occur in an indoor facility, outdoor facility, greenhouse facility, or a combination thereof;
- (D) The name of the owner of the premises upon which the business licensed is to be operated;
- (E) A statement that the applicant is in compliance with any applicable state or local laws, regulations, or ordinances;
- (F) A statement that the applicant has paid all state and local taxes that are due, as well as any additional fees imposed by law;
- (G) A summary of the applicant's business experience and a business plan meeting the criteria set out in this chapter; and
- (H) Any additional requirements based on the type of license the applicant is applying for as set forth in this chapter.

<u>005.05</u> <u>BUSINESS PLAN REQUIREMENTS.</u> A business plan submitted by an applicant must include the following:

- (A) Proof of financial capability to build, launch, and sustain cultivation, including access to capital, a detailed budget, and funding sources;
- (B) Facility design and operational readiness, including compliance with all applicable state laws and regulations and a demonstration of readiness to commence operations;
- (C) Demonstration of how the applicant meets the residency requirements in this chapter;
- (D) Any experience in operating a business in a regulated industry;
- (E) Any experience in cannabis cultivation, cannabis manufacturing, or cannabis retail;
- (F) Leadership team qualifications; and
- (G) Financial projections for the next year.

<u>005.06</u> <u>FALSE STATEMENTS.</u> If any false statement is made in any part of the application the license may be denied or revoked.

005.07 PROHIBITED PERSONS. A license shall not be issued to or held by:

- (A) Any person who has been convicted of any felony or any controlled substance related offense within the preceding ten (10) years;
- (B) An entity if any of its officers, directors, or owners have been convicted of any felony or any controlled substance related offense within the preceding ten (10) years;
- (C) An entity if any of its officers, directors, or owners have had a license or permit suspended or revoked pursuant to these regulations;
- (D) A person under the age of majority;
- (E) Any state, county, municipality, or other political subdivision, any branch, department, agency, or subdivision of any of the foregoing, or any corporation or other body established by law to carry out any government function;
- (F) A health care practitioner who has issued one or more written recommendations or written orders in the preceding five years; or
- (G) A person who has had any citation, fine, sanction, injunction or court judgment levied against the person, or a business owned by the person, involving cannabis or cannabinoid related operations or sales.
- <u>005.08</u> <u>LOCATION.</u> No cultivator license will be issued for any premises located within one thousand feet of any covered location. Except that this subsection shall not apply to any licensee operating an established registered cannabis establishment that was in operation prior to the covered location being established within one thousand feet of such establishment. One thousand feet will be measured in a straight line from the nearest property line of the covered location to the nearest perimeter wall of the licensed premises.
- <u>005.09</u> <u>LICENSEE RELOCATION.</u> A licensee shall not relocate a registered cannabis establishment from the place specified in the license.
- 005.10 LICENSE TRANSFER. Licenses are non-transferrable.
- <u>005.11</u> <u>NUMBER OF LICENSES ALLOWED.</u> No more than two (2) cultivator licenses shall be issued in the state. If during any calendar year the Commission finds the number of licensed cultivators is not sufficient to meet the demand for medical cannabis or medical cannabis products, the Commission may grant an additional one (1) cultivator license during the following year.

006. PRODUCT MANUFACTURER LICENSE APPLICATION.

- <u>006.01</u> <u>VERTICAL LICENSING.</u> Vertical licensing is not permitted. An applicant may not possess more than one license type authorized by this chapter.
- <u>006.02</u> <u>FINGER PRINTING.</u> An applicant for initial issuance of any license under this Chapter shall also submit two legible sets of fingerprints to be furnished for every person included in the application to the Nebraska State Patrol for a criminal history record information check and fee for such record check payable to the patrol. The applicant shall authorize the release of the criminal history record information check to the Commission.
- <u>006.03</u> <u>RESIDENCY REQUIREMENTS.</u> The following residency and citizenship requirements apply to any licensee applicant:

- (A) Must be majority owned by a United States citizen(s) who has been a resident(s) of Nebraska for no less than four years immediately preceding the application; and
- (B) Majority owned means more than fifty-one percent (51%) of the financial interests (other than a security interest, lien, or encumbrance) or more than fifty-one percent (51%) of the voting interests of an entity, including any parent and subsidiary entities.

006.04 REQUIRED INFORMATION. An application shall include the following:

- (A) The name and address of the applicant and if applicable, the applicant's officers, directors, or managers;
- (B) A statement that the applicant and the applicant's officers, directors, or managers satisfy the residency requirements provided in this chapter, and none have a disqualifying conviction;
- (C) The premises for which a license is desired, designating the premises by street and number, if practicable, or by such other description as to definitively locate the premises;
- (D) The name of the owner of the premises upon which the business licensed is to be operated;
- (E) A statement that the applicant is in compliance with any applicable state or local laws, regulations, or ordinances;
- (F) A statement that the applicant has paid all state and local taxes that are due, as well as any additional fees imposed by law;
- (G) A summary of the applicant's business experience and a business plan meeting the criteria set out in this chapter; and
- (H) Any additional requirements based on the type of license the applicant is applying for as set forth in this chapter.

<u>006.05</u> <u>BUSINESS PLAN REQUIREMENTS.</u> A business plan submitted by an applicant must include the following:

- (A) Proof of financial capability to build, launch, and sustain the product manufacturer, including access to capital, a detailed budget, and funding sources;
- (B) Facility design and operational readiness, including compliance with all applicable state laws and regulations and a demonstration of readiness to commence operations;
- (C) Demonstration of how the applicant meets the residency requirements in this chapter;
- (D) Any experience in operating a business in a regulated industry;
- (E) Any experience in cannabis cultivation, cannabis manufacturing, or cannabis retail;
- (F) Leadership team qualifications; and
- (G) Financial projections for the next year.

<u>006.06</u> <u>FALSE STATEMENTS.</u> If any false statement is made in any part of the application the license may be denied or revoked.

006.07 PROHIBITED PERSONS. A license shall not be issued to or held by:

- (A) Any person who has been convicted of any felony or any controlled substance related offense within the preceding ten (10) years;
- (B) An entity if any of its officers, directors, or owners have been convicted of any felony or any controlled substance related offense within the preceding ten (10) years;
- (C) An entity if any of its officers, directors, or owners have had a license or permit suspended or revoked pursuant to these regulations;
- (D) A person under the age of majority;

- (E) Any state, county, municipality, or other political subdivision, any branch, department, agency, or subdivision of any of the foregoing, or any corporation or other body established by law to carry out any government function;
- (F) A health care practitioner who has issued one or more written recommendations or written orders in the preceding five years; or
- (G) A person who has had any citation, fine, sanction, injunction or court judgment levied against the person, or a business owned by the person, involving cannabis or cannabinoid related operations or sales.
- <u>006.08</u> <u>LOCATION.</u> No manufacturer license will be issued for any premises located within one thousand feet of any covered location. Except that this subsection shall not apply to any licensee operating an established registered cannabis establishment that was in operation prior to the covered location being established within one thousand feet of such establishment. One thousand feet will be measured in a straight line from the nearest property line of the covered location to the nearest perimeter wall of the licensed premises.
- <u>006.09</u> <u>LICENSEE RELOCATION.</u> A licensee shall not relocate a registered cannabis establishment from the place specified in the license.
- <u>006.10</u> <u>LICENSE TRANSFER.</u> Licenses are non-transferrable.
- <u>006.11</u> <u>NUMBER OF LICENSES ALLOWED.</u> No more than four (4) product manufacturer licenses shall be issued in the state. If during any calendar year the Commission finds the number of licensed product manufacturers is not sufficient to meet the demand for medical cannabis or medical cannabis products, the Commission may grant an additional one (1) product manufacturer license during the following year.

007. TRANSPORTER LICENSE APPLICATION.

- <u>007.01</u> <u>VERTICAL LICENSING.</u> Vertical licensing is not permitted. An applicant may not possess more than one license type authorized by this chapter.
- <u>007.02</u> <u>FINGER PRINTING.</u> An applicant for initial issuance of any license under this Chapter shall also submit two legible sets of fingerprints to be furnished for every person included in the application to the Nebraska State Patrol for a criminal history record information check and fee for such record check payable to the patrol. The applicant shall authorize the release of the criminal history record information check to the Commission.
- <u>007.03</u> <u>RESIDENCY REQUIREMENTS.</u> The following residency and citizenship requirements apply to any licensee applicant:
 - (A) Must be majority owned by a United States citizen(s) who has been a resident(s) of Nebraska for no less than four years immediately preceding the application; and
 - (B) Majority owned means more than fifty-one percent (51%) of the financial interests (other than a security interest, lien, or encumbrance) or more than fifty-one percent (51%) of the voting interests of an entity, including any parent and subsidiary entities.
- 007.04 REQUIRED INFORMATION. An application shall include the following:
 - (A) The name and address of the applicant and if applicable, the applicant's officers, directors, or managers;

- (B) A statement that the applicant and the applicant's officers, directors, or managers satisfy the residency requirements provided in this chapter, and none have a disqualifying conviction;
- (C) The premises for which a license is desired, designating the premises by street and number, if practicable, or by such other description as to definitively locate the premises;
- (D) The name of the owner of the premises upon which the business licensed is to be operated;
- (E) A statement that the applicant is in compliance with any applicable state or local laws, regulations, or ordinances;
- (F) A statement that the applicant has paid all state and local taxes that are due, as well as any additional fees imposed by law;
- (G) A summary of the applicant's business experience and a business plan meeting the criteria set out in this chapter; and
- (H) Any additional requirements based on the type of license the applicant is applying for as set forth in this chapter.

<u>007.05</u> <u>BUSINESS PLAN REQUIREMENTS.</u> A business plan submitted by an applicant must include the following:

- (A) Proof of financial capability to build, launch, and sustain the transporter, including access to capital, a detailed budget, and funding sources;
- (B) Facility design and operational readiness, including compliance with all applicable state laws and regulations and a demonstration of readiness to commence operations;
- (C) Demonstration of how the applicant meets the residency requirements in this chapter;
- (D) Any experience in operating a business in a regulated industry;
- (E) Any experience in cannabis cultivation, cannabis manufacturing, or cannabis retail;
- (F) Leadership team qualifications; and
- (G) Financial projections for the next year.

<u>007.06</u> <u>FALSE STATEMENTS.</u> If any false statement is made in any part of the application the license may be denied or revoked.

007.07 PROHIBITED PERSONS. A license shall not be issued to or held by:

- (A) Any person who has been convicted of any felony or any controlled substance related offense within the preceding ten (10) years;
- (B) An entity if any of its officers, directors, or owners have been convicted of any felony or any controlled substance related offense within the preceding ten (10) years;
- (C) An entity if any of its officers, directors, or owners have had a license or permit suspended or revoked pursuant to these regulations;
- (D) A person under the age of majority;
- (E) Any state, county, municipality, or other political subdivision, any branch, department, agency, or subdivision of any of the foregoing, or any corporation or other body established by law to carry out any government function;
- (F) A health care practitioner who has issued one or more written recommendations or written orders in the preceding five years; or
- (G) A person who has had any citation, fine, sanction, injunction or court judgment levied against the person, or a business owned by the person, involving cannabis or cannabinoid related operations or sales.

<u>007.08</u> <u>LOCATION.</u> No Transporter license will be issued for any premises located within one thousand feet of any covered location. Except that this subsection shall not apply to any licensee operating an established registered cannabis establishment that was in operation prior to the covered location being established within one thousand feet of such establishment. One thousand feet will be measured in a straight line from the nearest property line of the covered location to the nearest perimeter wall of the licensed premises.

<u>007.09</u> <u>LICENSEE RELOCATION.</u> A licensee shall not relocate a registered cannabis establishment from the place specified in the license.

007.10 LICENSE TRANSFER. Licenses are non-transferrable.

007.11 NUMBER OF LICENSES ALLOWED. No more than one (1) transporter license shall be issued in any one district court judicial district as defined in Neb. Rev. Stat. § 24-301.02. If during any calendar year the Commission finds the number of licensed transporters in any district is not sufficient to meet the demand for medical cannabis or medical cannabis products, the Commission may grant an additional one (1) transporter license in the identified district or districts during the following year.

008. LICENSE RENEWAL OR SURRENDER FOR ALL LICENSE TYPES.

<u>008.01</u> <u>RENEWAL APPLICATION PROCESS.</u> A licensee may apply for renewal at least thirty (30) calendar days, but no sooner than ninety (90) calendar days, prior to the expiration date of an existing license. A registered cannabis establishment licensee which is not renewing an existing license must provide written notice of non-renewal to the Commission no later than thirty (30) calendar days prior to the expiration date of the existing license.

<u>008.02</u> <u>FINGER PRINTING.</u> An applicant for renewal of any license under this Chapter shall also submit two legible sets of fingerprints to be furnished for every person included in the application to the Nebraska State Patrol for a criminal history record information check and fee for such record check payable to the patrol. The applicant shall authorize the release of the criminal history record information check to the Commission.

<u>008.03</u> <u>RESIDENCY REQUIREMENTS.</u> The following residency and citizenship requirements apply to any licensee renewal applicant:

- (A) Must be majority owned by a United States citizen(s) who has been a resident(s) of Nebraska for no less than four years immediately preceding the application; and
- (B) Majority owned means more than fifty-one percent (51%) of the financial interests (other than a security interest, lien, or encumbrance) or more than fifty-one percent (51%) of the voting interests of an entity, including any parent and subsidiary entities.

<u>008.04</u> <u>REQUIRED INFORMATION.</u> An application for any type of license renewal shall include the following:

- (A) The name and address of the applicant and if applicable, the applicant's officers, directors, or managers;
- (B) A statement that the applicant and the applicant's officers, directors, or managers satisfy the residency requirements provided in this chapter, and none have a disqualifying conviction;
- (C) The premises for which a license is desired, designating the premises by street and number, if practicable, or by such other description as to definitively locate the premises;

- (D) The name of the owner of the premises upon which the business licensed is to be operated;
- (E) A statement that the applicant is in compliance with any applicable state or local laws, regulations, or ordinances;
- (F) A statement that the applicant has paid all state and local taxes that are due, as well as any additional fees imposed by law;
- (G) A business plan meeting the criteria set out in this chapter; and
- (H) Any additional requirements based on the type of license the applicant is applying for as set forth in this chapter.
- <u>008.05</u> <u>BUSINESS PLAN REQUIREMENTS.</u> A business plan submitted by an applicant must include the following:
 - (A) Proof of financial capability to sustain the registered cannabis establishment, including access to capital, a detailed budget, and funding sources;
 - (B) Facility design and operational readiness, including compliance with all applicable state laws and regulations;
 - (C) Demonstration of how the applicant meets the residency requirements in this chapter;
 - (D) Leadership team qualifications; and
 - (E) Financial projections for the next year.
- <u>008.06</u> <u>FALSE STATEMENTS.</u> If any false statement is made in any part of the renewal application the license may be denied or revoked.
- 008.07 PROHIBITED PERSONS. A license shall not be granted to, renewed to or held by:
 - (A) Any person who has been convicted of any felony or any controlled substance related offense within the preceding ten (10) years;
 - (B) An entity if any of its officers, directors, or owners have been convicted of any felony or any controlled substance related offense within the preceding ten (10) years;
 - (C) An entity if any of its officers, directors, or owners have had a license or permit suspended or revoked pursuant to these regulations;
 - (D) A person under the age of majority;
 - (E) Any state, county, municipality, or other political subdivision, any branch, department, agency, or subdivision of any of the foregoing, or any corporation or other body established by law to carry out any government function;
 - (F) A health care practitioner who has issued one or more written recommendations or written orders in the preceding five years; or
 - (G) A person who has had any citation, fine, sanction, injunction or court judgment levied against the person, or a business owned by the person, involving cannabis or cannabinoid related operations or sales.
- <u>008.08</u> <u>LICENSE SURRENDER.</u> A registered cannabis establishment may surrender a license prior to expiration of the license term. To properly surrender a license an establishment must:
 - (i) Give at least thirty (30) day advance written notice to the Commission; and
 - (ii) Ensure proper collection and disposal of all medical cannabis or medical cannabis products prior to the license being surrendered.
 - <u>008.08(A)</u> <u>IMMEDIATE REVOCATION.</u> Failure to provide proper notice may result in immediate revocation.

<u>008.08(B)</u> <u>VOLUNTARY NON-RENEWAL.</u> For purposes of this chapter, the voluntary non-renewal of a registered cannabis establishment license is considered the surrender of a license.

<u>008.08(C)</u> <u>FUTURE LICENSE DETERMINATIONS.</u> A license properly surrendered is not a sanction or revocation for purposes of future license determinations under this chapter.

009. LICENSE DENIAL.

<u>009.01</u> <u>DENIAL.</u> In addition to the other factors and requirements set forth in the Nebraska Medical Cannabis Regulation Act and these regulations, the Commission may deny issuance or renewal of a license for good cause.

<u>009.02</u> <u>GOOD CAUSE.</u> For purposes of this section, good cause means:

- (A) The licensee or applicant has violated the Nebraska Medical Cannabis Regulation Act or rules and regulations adopted and promulgated thereunder, particularly when such violations adversely affect public health or safety;
- (B) The licensee or applicant has made materially false statement to the Commission;
- (C) The licensee or applicant has failed to comply with any special terms or conditions that were placed on its license pursuant to an order of the Commission;
- (D) The license would otherwise violate conditions contained in this chapter;
- (E) The licensee or applicant is not in compliance with state, federal, or local laws or ordinances:
- (F) The licensee has not paid all state and local taxes that are due, as well as any additional fees imposed by law;
- (G) The licensee had a license sanctioned or revoked under this chapter;
- (H) The licensee had a similar license sanctioned or revoked in another United States state or territory;
- (I) The licensee failed to properly surrender a license issued under this chapter; or
- (J) The application is not complete.

010. LICENSE SANCTIONS.

- <u>010.01</u> <u>SANCTIONS.</u> A licensee may be sanctioned by the Commission for violations of this chapter or the Nebraska Medical Cannabis Regulation Act. Sanctions may include:
 - (A) License suspension;
 - (B) Licenses revocation:
 - (C) Fines:
 - (D) Limitations upon license:
 - (E) Terms of probation;
 - (F) Seizure or destruction of any cannabis, cannabis products, or cannabis accessories; or
 - (G) Any combination of the above.
- <u>010.02</u> <u>INACTIVE REGISTERED CANNABIS ESTABLISHMENT.</u> If a registered cannabis establishment has been inactive, without good cause, for six (6) or more months the Commission may revoke, cancel or elect not to renew the license of the registered cannabis establishment.

<u>010.03</u> <u>CONVICTIONS.</u> A registered establishment's license may be revoked if the license holder is convicted of any felony or any controlled substance related offense during the term of the license.

<u>010.04</u> <u>LOCAL COMPLIANCE.</u> A registered establishment's license may be sanctioned if the license holder or the establishment fails to comply with applicable state or local government requirements.

011. APPEALS.

<u>O11.01</u> <u>APPEALS OF COMMISSION ACTIONS.</u> A licensee may appeal a decision of the Commission to deny a license or to sanction a license or licensee by requesting a fair hearing in accordance with the Nebraska Administrative Procedures Act. A request to appeal must be submitted in writing to the Commission within ten (10) business days of the action to be appealed. Hearings will be conducted in accordance with the Nebraska Administrative Procedures Act.

<u>011.02</u> <u>MODEL RULES ADOPTED.</u> The Commission follows the model rules adopted by the Attorney General for practice and procedure governing hearings in contested cases found in Title 53 Nebraska Administrative Code (NAC).

012. REGISTERED CANNABIS ESTABLISHMENT MANAGEMENT STANDARDS.

- <u>012.01</u> <u>MANAGER.</u> Each licensee shall personally manage the licensed registered cannabis establishment or employ a separate and distinct manager for the licensed registered cannabis establishment and shall report the name of the manager to the Commission.
- <u>012.02</u> <u>MANAGEMENT CHANGE.</u> The licensee shall report any change in manager to the Commission in the manner provided by the Commission.
- <u>012.03</u> <u>LICENSE PUBLISHING.</u> A licensee shall possess and maintain a copy of the license in a conspicuous place visible to the public on the licensed premises.
- <u>012.04</u> <u>MINORS ON PREMISES.</u> No licensee shall allow any individual under the age of eighteen (18) on or in any licensed premises.
- <u>012.05</u> <u>CONSUMPTION ON PREMISIS.</u> No licensee shall allow the consumption or use of any cannabis or cannabis products on or in any licensed premises.
- <u>012.06</u> <u>EMPLOYEES OR AGENTS.</u> No licensee shall employ or maintain as an employee or agent a prohibited person as set forth in this chapter.
- <u>012.07</u> <u>SECURITY REQUIREMENTS.</u> All registered cannabis establishments shall implement appropriate security measures to deter and prevent the unauthorized entrance into areas containing medical cannabis and the theft and diversion of medical cannabis and medical cannabis products. All establishments shall develop a comprehensive security plan. At a minimum, a security plan shall include a 24 hours per day, seven (7) days per week interior and exterior video monitoring and intrusion detection monitoring system, recording and video storage capabilities for all facilities, and licensed security personnel. The entire premises shall be equipped with a centralized access control system capable of generating detailed reports of access logs for a minimum of one year. All videos, access logs, and any

other monitoring data shall be available to the Nebraska State Patrol, any other law enforcement agency, or the Commission upon request. Establishments shall also develop a written plan detailing specific security measures to ensure secure transportation and tracking of delivered products for intra-facility transportation.

<u>012.07(A)</u> <u>RESPONSIBLE ENTITY.</u> Licensees are responsible for the security of all medical cannabis items on the licensed premises or all medical cannabis items in their possession during transit.

<u>012.07(B)</u> <u>THEFT DETERRENCE.</u> Licensees shall provide effective controls and procedures to guard against theft and diversion of medical cannabis and medical cannabis products.

<u>012.07(C)</u> <u>WASTE STORAGE.</u> Licensees shall store all medical cannabis waste in a secure waste receptacle that is locked with commercial-grade locks prior to disposal or transfer. The receptacle shall be kept in a safe and secure location with limited access.

<u>012.08</u> <u>SEED-TO-SALE SYSTEM.</u> A registered cannabis establishment must utilize a seed-to-sale system as required by this subsection.

<u>012.08(A) MANDATORY USAGE</u>. Prior to the implementation of a state inventory tracking system a registered cannabis establishment shall use a Commission-approved seed-to-sale tracking system. Upon implementation of the state inventory tracking system, no registered cannabis establishment shall sell or otherwise transfer, purchase, obtain or otherwise accept the transfer of medical cannabis or otherwise accept the transfer of medical cannabis or medical cannabis products that are not properly inputted and tracked in the state inventory tracking system.

<u>012.08(B)</u> <u>OPTIONAL USAGE.</u> Upon implementation of the state inventory tracking system registered cannabis establishments may continue to use a Commission approved seed-to-sale tracking system. A seed-to-sale system should integrate fully with the state inventory tracking system. If the seed-to-sale system does not integrate with the state inventory tracking system or does integrate but does not share all required information, the registered cannabis establishment shall ensure all required information is reported directly into the State inventory tracking system.

<u>012.09</u> <u>RECLAMATION BOND REQUIREMENTS.</u> Registered cannabis establishments shall, no later than thirty (30) calendar days after being issued a license, file with the Commission a bond covering the licensed premises. The bond must meet the following requirements:

- (i) A reclamation bond in an amount of no less than two ene hundred thousand dollars (\$200,000.00), to cover the costs of reclamation or to defray the cost of restoration of the property including removing equipment, destruction of waste, remediation of environmental hazards, prohibiting public access, addressing improperly coded buildings, or determination of the final disposition of any seized property;
- (ii) Name the State of Nebraska as the secured party; and
- (iii) Be issued by a surety company qualified to do business in Nebraska as a surety.
 - (1) For purposes of this subsection, "qualified" means a business that has a Certificate of Authority, License, or other formal authorization from the Nebraska Department of Insurance authorizing the surety to transact business in Nebraska.

- <u>012.10</u> <u>PERFORMANCE BOND REQUIREMENTS</u>. Registered cannabis establishments shall, no later than thirty (30) calendar days after being issued a license, file with the Commission a bond covering the lawful operation of the establishment. The bond must meet the following requirements:
 - (i) A performance bond in an amount of no less than one hundred thousand dollars (\$100,000.00) to cover the costs of ensuring the lawful operations of the registered cannabis establishment, including compliance with this chapter;
 - (ii) Name the State of Nebraska as the secured party; and
 - (iii) Be issued by a surety company qualified to do business in Nebraska as a surety.
 - (1) For purposes of this subsection, "qualified" means a business that has a Certificate of Authority, License, or other formal authorization from the Nebraska Department of Insurance authorizing the surety to transact business in Nebraska.
- <u>012.11</u> <u>ADDITIONAL BOND REQUIREMENTS.</u> All registered cannabis establishments must comply these additional bond requirements.
 - <u>012.11(A)</u> <u>BOND EXPIRATION.</u> No later than thirty (30) calendar days prior to the expiration date of a required bond, a registered cannabis establishment shall provide proof to the Commission that the bond has been renewed, or a new bond has been issued in the required amount.
 - <u>012.11(B)</u> <u>CANCELLED BOND</u>. Upon cancellation of a required bond, the registered cannabis establishment shall provide proof to the Commission of a new, alternate bond before the termination date of the previous bond.
 - <u>012.11(C)</u> <u>BOND DURATION.</u> A claim may be filed against a required bond up to one (1) year after revocation or surrender of the license or cancellation or expiration of the bond.
- <u>012.12</u> <u>PRIVATE LEGAL REMEDIES.</u> Nothing in this chapter shall prevent a landlord or landowner from requiring an additional bond or other form of security for purpose of renting or leasing real property to a registered cannabis establishment. Nor does this chapter limit any other private legal remedies.
- <u>012.13</u> <u>REQUIRED NOTIFICATION.</u> A registered cannabis establishment shall notify the Commission within three (3) business days of the following:
 - (A) The initiation or conclusion of any new citations, fines, judgments, lawsuits, legal proceedings, charges, or government investigations, involving cannabis-related operations, whether initiated, pending, or concluded, against the licensee and its owners in Nebraska and in any other state:
 - (B) An adverse event report from a qualified patient, caregiver, or other registered cannabis establishment;
 - (C) Any change in the hours of operation, including temporary closures;
 - (D) Any suspected theft or attempted theft of medical cannabis from the registered cannabis establishment;
 - (E) Any change in manager; or
 - (F) Any licensee, manager, employee, agent, or any member with an economic interest in the registered cannabis establishment is charged with a disqualifying offense.
- <u>012.14 ADVERSE EVENT REPORTING.</u> Adverse event reports shall be submitted utilizing the Commission-approved form.

013. DISPENSARY REQUIREMENTS.

<u>013.01</u> <u>POSSESSION FOR SALE OR TRANSFER.</u> A dispensary may only possess, sell or transfer cannabis for medical purposes, as defined by Neb. Rev. Stat § 71-24,107, or those purposes expressed in this chapter. A dispensary shall not give away or otherwise offer or transfer cannabis as part of a promotional event.

<u>013.02</u> <u>CANNABIS PRODUCT.</u> A dispensary may only obtain cannabis products from a Nebraska licensed transporter or a Nebraska licensed manufacturer. A dispensary may not possess, dispense, or cause to be transported any cannabis product that is not allowed under this chapter.

013.03 ELECTRONIC DELIVERY SYSTEM. A dispensary must establish a system to receive written recommendations and written orders in electronic form directly from the health care practitioner. A dispensary must retain all written recommendations and written orders received through its established electronic system for no less than seven (7) years. Written recommendations and written orders must be from a health care practitioner enrolled in the Recommending Health Care Practitioner Directory in accordance with this chapter.

<u>013.03(A)</u> <u>COMMISSION ACCESS</u>. A dispensary must provide the Commission real-time direct access to the dispensary's electronic delivery system.

<u>013.04</u> <u>SALE OR TRANSFER.</u> A dispensary may only sell or transfer medical cannabis or medical cannabis products at the licensed premises and may not deliver or otherwise transport to a qualified patient or caregiver. A dispensary may not sell or transfer medical cannabis to a qualified patient or caregiver unless the dispensary has received an electronic copy of the written recommendation issued within the last twenty-four (24) months and written order for the medical cannabis directly from the recommending health care practitioner. The written recommendation must comport with the requirements contained in the Neb. Rev. Stat. § 71-24,104, and the written order must comport with the requirements of this chapter. A dispensary must verify the identity of the qualified patient or caregiver by requiring a state or government issued photo identification or a student photo identification issued by a Nebraska College or University.

<u>013.04(i)</u> <u>LABELING REQUIREMENT.</u> All medical cannabis or medical cannabis products sold or transferred by a dispensary must have an affixed label which includes the name of the qualified patient, the recommending health care practitioner, the name of dispensary, the dispensary's address and phone number, and the name of the medical cannabis product.

<u>013.05</u> <u>QUALIFIED PATIENT REQUIREMENT.</u> A dispensary shall only sell or transfer medical cannabis to the qualified patient, who is eighteen (18) years of age or older, if the patient has a valid, unexpired written recommendation which includes the requirements contained in Neb. Rev. Stat. § 71-24,104. A dispensary shall only sell or transfer medical cannabis to the qualified patient as specified in the valid, unexpired written order which includes the requirements contained in this chapter.

<u>013.06</u> <u>CAREGIVER REQUIREMENT.</u> A dispensary shall only sell or transfer medical cannabis to a caregiver under the following circumstances:

(A) When the qualified patient is at least eighteen (18) years of age and the caregiver has been designated by the qualified patient in a signed affidavit;

- (B) When the qualified patient is under eighteen (18) years of age and the caregiver is the legal guardian or parent of the qualified patient and produces a signed attestation that meets the requirements of this chapter, or the caregiver is a person designated by the legal guardian or parent of the qualified patient in a sworn affidavit with the authority to make health care decisions on behalf of the qualified patient; or
- (C) A health care facility or home health agency which meets the requirements set forth in Neb. Rev. Stat. § 71-24,104.

<u>013.06(i)</u> <u>AFFIDAVIT REQUIREMENTS.</u> Affidavits must meet the following requirements:

- (1) When the qualified patient is at least eighteen (18) years of age and designates a caregiver:
 - (a) The full legal name and age of the qualified patient;
 - (b) The full legal name and age of the caregiver;
 - (c) A statement designating the named individual as the caregiver; and
 - (d) The dated, notarized signature of the qualified patient;
- (2) When the qualified patient is under eighteen (18) years of age or the qualified patient under the protection of a legal guardian and the parent or legal guardian designates a caregiver:
 - (a) The full legal name and age of the qualified patient;
 - (b) The full legal name of the parent or legal guardian;
 - (c) The nature of the parent or legal guardian's relationship to the qualified patient and a statement asserting authority to make health care decisions for the qualified patient;
 - (d) The full legal name and age of the caregiver;
 - (e) A statement designating the named individual as the caregiver; and
 - (f) The dated, notarized signature of the authorizing parent or legal guardian; or
- (3) When the caregiver is a health care facility or home health agency:
 - (a) The full legal name and age of the qualified patient;
 - (b) When the qualified patient is under eighteen (18) years of age or is under the care of parent or legal guardian, the full legal name of the authorizing parent or legal guardian;
 - (c) When the qualified patient is under eighteen (18) years of age or is under the care of parent or legal guardian, the nature of the parent or legal guardian's relationship to the qualified patient and a statement asserting authority to make health care decisions for the qualified patient;
 - (d) The health care facility or home health agency to be designated as the caregiver;
 - (e) A statement designating the named entity as the caregiver; and
 - (f) The dated, notarized signature of the authorizing patient or authorizing parent or legal guardian.

<u>013.06(ii)</u> <u>ATTESTATION REQUIREMENTS.</u> A signed attestation must contain the following:

- (1) The full legal name of the qualified patient;
- (2) The full legal name of the parent or legal guardian;
- (3) The nature of the relationship to the patient; and
- (4) The dated signature of the parent or legal guardian.

- QUANTITY REQUIREMENT. A dispensary may not sell or transfer any amount of medical cannabis that would result in the qualified patient or caregiver possessing more than five (5) ounces as allowed by Neb. Rev. Stat. § 71-24,104, or more than the amount contained in the written order if less than five (5) ounces. A dispensary may not sell or transfer to a qualified patient or caregiver more than a 30-day supply of medical cannabis based on the dosage rate in the written order. A dispensary may not sell or transfer more than five (5) grams of delta-9-tetrahydrocannabinol (delta-9-THC) to the same qualified patient or for the same qualified patient in a ninety (90) day period. A dispensary shall not sell or transfer to a qualified patient or care giver any medical cannabis within thirty (30) days after filling a valid written order.
- <u>013.08</u> <u>NO REFILLS.</u> A dispensary may not sell or transfer medical cannabis to the same qualified patient for the same written order more than once.
- <u>013.09</u> <u>DISPENSABLE PRODUCTS.</u> A dispensary shall not sell or transfer any cannabis or cannabis product that that does not meet the requirements of this chapter.
 - <u>013.09(A)</u> <u>ALLOWABLE PRODUCTS.</u> The following product types or formulations are allowed:
 - (i) Oral tablets, capsules, or tinctures;
 - (ii) Gels, oils, creams, or other topical preparation;
 - (iii) Suppositories;
 - (iv) Transdermal patches; or
 - (v) Liquids or oils for administration using a nebulizer or inhaler.
 - <u>013.09(B)</u> <u>UNALLOWABLE PRODUCTS.</u> The following product types or formulations are not allowed:
 - (i) Raw plant material;
 - (ii) Any product administered by smoking, combustion, or vaping;
 - (iii) Any product containing artificial flavoring, natural flavoring, or coloring;
 - (iv) A food or drink that has cannabis baked, mixed, or otherwise infused into it;
 - (v) Any product that includes a synthetic or converted cannabinoid;
 - (vi) Any product that exceeds a potency of 60% delta-9-tetrahydrocannabinol (delta-9-THC) or a dose of 40 mg per dose;
 - (vii) Any product or packaging which would reasonably cause confusion as to whether the cannabis product is a food product;
 - (viii) Any product in the shape of a human, animal, marijuana leaf; or
 - (ix) Any tobacco, alcohol, or other intoxicating substance; or
 - (x) Any product that is not a medical cannabis or a medical cannabis product registered with the Commission.
- <u>013.10</u> <u>RECALL.</u> A dispensary may voluntarily recall products that don't meet product specifications contained in this chapter or that the dispensary or manufacturer determines should be recalled for public safety.
- <u>013.11</u> <u>DISPOSAL OF MEDICAL CANNABIS AND PLANT MATERIAL.</u> A dispensary shall return medical cannabis waste to a product manufacturer for disposal. A dispensary must maintain a written record of all medical cannabis returned to the product manufacturer for disposal.

- <u>013.12</u> <u>DISPOSAL REQUIREMENTS.</u> Pending return to a product manufacturer, a dispensary shall store, secure, manage, and record medical cannabis waste in accordance with all applicable federal, state, and local regulations.
- <u>013.13</u> <u>RECORD REQUIREMENTS FOR DISPENSARIES.</u> Registered establishments dispensing medical cannabis products to qualified patients or qualified caregivers must retain the following records for no less than seven (7) years:
 - (A) Copies of all documents required under this chapter for sale or transfer of medical cannabis:
 - (B) Sales invoices or receipts for all sales or transfers of medical cannabis, which shall include the following:
 - (i) Name and address of purchaser;
 - (ii) Date of sale and invoice number;
 - (iii) Item, category, and quantity of cannabis sold;
 - (iv) The cost to the purchaser, together with any discount applied to the price as shown on the invoice;
 - (v) The place from which transport of the cannabis was made unless transport or delivery was made from the premises of the licensee;
 - (vi) Seller's name, license number and address; and
 - (vii) Any associated manifests from transporter;
 - (C) Daily inventory records which shall include the following;
 - (i) The type, quantity and potency of all medical cannabis products;
 - (ii) Daily transactions, including electronically received written orders for each sale or transfer to medical cannabis to a qualified patient or caregiver; and
 - (iii) Any discrepancies between the daily inventory and daily transactions;
 - (D) A medical cannabis waste disposal log indicating the date and time, the name of the product manufacturer, the name of the product, and the amount of medical cannabis the product manufacturer received for destruction; and
 - (E) Records of all purchases of inventory and stock for purposes of sale or transfer which include:
 - (i) Transport manifests; and
 - (ii) The name and license number of all cultivators or manufacturers for all products sold, transferred, or purchased by the establishment for sale or transfer.

014. CULTIVATOR REQUIREMENTS.

- <u>014.01</u> <u>POSSESSION FOR CULTIVATION.</u> A cultivator may only possess, cultivate or process cannabis for medical purposes, as defined by Neb. Rev. Stat. § 71-24,107, or those purposes expressed in this chapter.
- <u>014.02</u> <u>CULTIVATION FOR SALE OR TRANSFER.</u> A cultivator may only cultivate or process cannabis for sale or transport to a Nebraska licensed product manufacturer or other Nebraska licensed cultivator.
- <u>014.03</u> <u>LOCATION.</u> All cultivation of medical cannabis shall take place at the premises identified in the cultivator license. Cultivation may occur in outdoor, indoor, or greenhouse facilities or any combination of these cultivation practices.
- <u>014.04</u> <u>LOCATION ACCESS.</u> Cultivation locations must be secured to reasonably prevent access to any cannabis plants or products by animals, or individuals who are not authorized agents of the cultivator or otherwise authorized access by law.

- <u>014.05</u> <u>SIGNAGE</u>. Licensed cultivators shall erect and maintain signage at the site of the cultivation locations that must be visible from the road at the primary entrance to the grow facility.
 - <u>014.05(A)</u> <u>PRIMARY ENTRANCE.</u> Primary entrance means the principal or main entrance of the cultivation facility which is used by staff or persons accessing the property.
 - <u>014.05(B)</u> <u>SIGNAGE REQUIREMENTS.</u> The signage shall be located at the perimeter of the property with dimensions measuring no less than eighteen (18) inches by twenty-four (24) inches with a font size of no less than two (2) inches and must meet the following requirements:
 - (i) Information required to be displayed on the sign shall be in black standardized font on a white background;
 - (ii) The signage shall comply with county regulations and local ordinances related to the real property where the cultivation facility is located; and
 - (iii) The following information shall be included:
 - (a) Business name;
 - (b) Physical address of the licensed business;
 - (c) Phone number of the licensed business; and
 - (d) Cultivator license number.
 - <u>014.05(C) PERIMETER.</u> Perimeter of the property refers to the outermost boundaries of the property that is licensed by the Commission as a cultivator.
- <u>014.05</u> <u>RELIABLE AND ONGOING SUPPLY.</u> Cultivators shall provide a reliable and ongoing supply of medical cannabis sufficient to meet the needs of licensed manufacturers and licensed dispensaries in Nebraska.
- <u>014.06 CHEMICAL RESTRICTIONS.</u> A cultivator may not use pesticides, herbicides, or fertilizers other than those certified organic by the Organic Materials Review Institute or another similar standards organization. No other chemicals may be used for the purposes of planting, growing, or cultivating medical cannabis.
- <u>014.07</u> <u>TESTING.</u> A cultivator may provide cannabis samples to a testing facility for testing and research for development purposes.
- <u>014.08</u> <u>SEED OR PLANT STOCK.</u> A cultivator may only obtain cannabis seeds, immature cannabis plants, or cannabis genetic material from another Nebraska licensed cultivator or a cultivator authorized to operate in another state of the United States.
- <u>014.09</u> <u>RECALL.</u> A cultivator may voluntarily recall products that don't meet product specifications contained in this chapter or that the cultivator determines should be recalled for public safety.
- <u>014.10</u> <u>DISPOSAL OF MEDICAL CANNABIS AND PLANT MATERIAL.</u> A cultivator must maintain a written record of all medical cannabis waste disposed of in accordance with this chapter.

<u>014.11 DISPOSAL REQUIREMENTS.</u> A cultivator shall store, secure, manage, and record medical cannabis waste and plant material waste in accordance with all applicable federal, state, and local regulations. Before transport of plant material waste, the cultivator shall render the plant material waste unusable and unrecognizable.

<u>014.12</u> <u>RECORDS REQUIRED FOR CULTIVATORS.</u> Cultivators must retain the following records for no less than seven (7) years:

- (A) Sales invoices or receipts for all sales or transfers of medical cannabis, which shall include the following:
 - (i) Name and address of purchaser;
 - (ii) Date of sale and invoice number;
 - (iii) Item, category, and quantity of cannabis sold;
 - (iv) The cost to the purchaser, together with any discount applied to the price as shown on the invoice:
 - (v) The place from which transport of the cannabis was made unless transport or delivery was made from the premises of the licensee;
 - (vi) Seller's name, license number and address; and
 - (vii) Any associated manifests from transporter;
- (B) Daily inventory records which shall include the following:
 - (i) The type, quantity and potency of all medical cannabis products;
 - (ii) Daily transactions; and
 - (iii) Any discrepancies between the daily inventory and daily transactions; and
- (C) Records of all purchases of inventory or stock for purposes of sale or transfer which include:
 - (i) Transport manifests; and
 - (ii) The name and license number of all cultivators or manufacturers for all products sold or transferred, or purchased by the establishment for sale or transfer;
- (D) When cannabis seeds are planted;
- (E) When each cannabis plant is in a vegetative state, harvested, transferred, transported, processed, destroyed or sold;
- (F) Description of each cannabis plant type cultivated to include type, delta-9-tetrahydrocannabinol (delta-9-THC) content, and delta-9-tetrahydrocannabinol (delta-9-THC) potency;
- (G) All organic pesticides, herbicides, or fertilizers applied to cannabis plants or growing medium during cultivation and all ingredients contained in any organic pesticides, herbicides, or fertilizers applied to cannabis plants or growing medium during cultivation:
- (H) All samples provided to a testing facility, the identity and address of the testing facility, and test results;
- (I) A medical cannabis waste disposal log indicating the date and time, location, method of destruction, mixing medium, and agent ID(s) of the employee(s) who destroyed the cannabis product; and
- (J) The source of all cannabis seeds purchased, including the name of seller, contact information, state of origin, and proof of authorization to operate a cannabis business in that state.

015. PRODUCT MANUFACTURER REQUIREMENTS.

<u>015.01</u> <u>POSSESSION FOR MANUFACTURING.</u> A manufacturer may only possess, manufacture or process cannabis for medical purposes, as defined by Neb. Rev. Stat. § 71-24,107, or those purposes expressed in this chapter. A product manufacturer may not

manufacture a final product or cause to be transported any cannabis product with a delta-9-tetrahydrocannabinol (delta-9-THC) potency greater than 60%.

- <u>015.02</u> <u>MANUFACTURING FOR SALE OR TRANSFER.</u> A manufacturer may only manufacture, possess or process cannabis for sale or transport to a Nebraska licensed dispensary, another Nebraska licensed product manufacturer, or Nebraska licensed cultivator.
- <u>015.03</u> <u>LOCATION.</u> All manufacturing of medical cannabis shall take place at the premise identified in the manufacturing license.
- <u>015.04</u> <u>LOCATION ACCESS.</u> Manufacturing locations must be secured to reasonably prevent access to any cannabis plants or products by animals, or individuals who are not authorized agents of the manufacturer or otherwise authorized access by law.
- <u>015.05</u> <u>TESTING.</u> A manufacturer may provide cannabis or cannabis product samples to a testing facility for testing and research for development purposes.
- <u>015.06</u> <u>CANNABIS SEED, CANNABIS PLANT STOCK OR CANNABIS PRODUCT.</u> A manufacturer may only obtain cannabis plants or cannabis products from a Nebraska licensed cultivator or another Nebraska licensed manufacturer.
- <u>015.07</u> <u>ALLOWABLE PRODUCTS.</u> A manufacturer may only manufacture or produce products allowed to be sold or transferred by Nebraska licensed dispensaries to qualified patients or caregivers as set forth in this chapter.
 - <u>015.07(A) PRODUCT REGISTRATION.</u> A manufacturer must register each medical cannabis product with the Commission. To register a product, the manufacturer must submit the following to the Commission:
 - (i) Certificate of analysis completed within the last 90 days;
 - (ii) Potency and total amount of the delta-9-tetrahydrocannabinol (delta-9-THC) in the product;
 - (iii) A description of the manufacturing process, including the name and amount of all ingredients;
 - (iv) Intake instructions:
 - (v) Product package design;
 - (vi) Product label, which shall not be required to contain an expiration date at the time of application; and
 - (vii) The dispensary in which the product manufacturer intends to sell the proposed products.
 - <u>015.07(B)</u> <u>PRODUCT TESTING.</u> A manufacturer must submit each medical cannabis product intended to be registered with the Commission for testing by a testing facility accredited under the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) standard 17025: 2017 standard. The scope of the accreditation shall include all cannabis product testing required by this chapter. The testing facility must be approved by the Commission. The testing conducted on each product must comport with the testing requirements in this chapter.
 - <u>015.07(C)</u> <u>TESTING RESULTS.</u> A manufacturer must submit the required testing results for each unique medical cannabis product lot intended to be registered to the Commission.

<u>015.07(D)</u> <u>PRODUCT REGISTRATION EXPIRATION.</u> A product registration will expire one (1) year after submission to the Commission.

<u>015.07(E)</u> <u>PRODUCT REGISTRATION RENEWAL.</u> A manufacturer may re-register a product no later than thirty (30) days, but no sooner than ninety (90) days, prior to the expiration date of the existing product registration. To re-register a product, the manufacturer must submit the following to the Commission:

- (i) Certificate of analysis completed within the last ninety (90) days;
- (ii) Potency and total amount of the delta-9-tetrahydrocannabinol (delta-9-THC) in the product;
- (iii) Any proposed changes to the intake instructions, product packaging design, or product label; and
- (iv) The following product data:
 - (1) Which dispensaries the product was sold;
 - (2) How much of the product was manufactured, and
 - (3) How much of the product the manufacturer has possession of at the time of the renewal.

<u>015.08</u> <u>PACKAGING.</u> A product manufacturer may only sell or transfer products that are sealed and comport with the following:

- (A) The package shall protect the product from contamination and shall not expose the product to any toxic or harmful substance; and
- (B) The package shall be tamper-evident, which means the product shall be packaged in a container within which a product is sealed so that the contents cannot be opened without obvious destruction of the seal.
- <u>015.09</u> <u>FOOD SAFETY STANDARDS.</u> A product manufacturer must comply with all applicable laws regarding food standards. All ingredients, other than those naturally occurring in cannabis, shall be approved by the U.S. Food and Drug Administration.
- <u>015.10</u> <u>RECALL.</u> A product manufacturer may voluntarily recall products that don't meet product specifications contained in this chapter or that the manufacturer determines should be recalled for public safety.
- <u>015.11</u> <u>DISPOSAL OF MEDICAL CANNABIS AND PLANT MATERIAL.</u> A product manufacturer may collect at no charge medical cannabis waste from Nebraska licensed dispensaries. A product manufacturer must record the name of the product, the time and date of the return, and the name of the dispensary from which it received a returned product. A product manufacturer that collects medical cannabis waste may use it for research and development or retained samples, but the manufacturer shall not introduce medical cannabis returned from a dispensary or testing facility into lots of products intended for sale or transport. A manufacturer shall dispose of medical cannabis waste not being used or retained as allowed by this section and maintain a written record of disposal.
- <u>015.12</u> <u>DISPOSAL REQUIREMENTS.</u> A product manufacturer shall store, secure, manage, and record medical cannabis waste and plant material waste in accordance with all applicable federal, state, and local regulations. Before transport of plant material waste, the manufacturer shall render the plant material waste unusable and unrecognizable. A product manufacturer shall dispose of all liquid and chemical product waste generated in the process of

manufacturing medical cannabis in accordance with applicable federal, state and local regulations.

<u>015.13</u> <u>RECORDS REQUIRED FOR MANUFACTURERS.</u> Manufacturers must retain the following records for no less than seven (7) years:

- (A) Sales invoices or receipts for all sales or transfers of medical cannabis, which shall include the following:
 - (i) Name and address of purchaser;
 - (ii) Date of sale and invoice number;
 - (iii) Item, category, and quantity of cannabis product sold;
 - (iv) The cost to the purchaser, together with any discount applied to the price as shown on the invoice;
 - (v) The place from which transport of the cannabis was made unless transport or delivery was made from the premises of the licensee;
 - (vi) Seller's name, license number and address; and
 - (vii) Any associated manifests from transporter;
- (B) Daily inventory records which shall include the following;
 - (i) The type, quantity and potency of all medical cannabis products;
 - (ii) Daily transactions; and
 - (iii) Any discrepancies between the daily inventory and daily transactions; and
- (C) Records of all purchases of inventory or stock for purposes of sale or transfer which includes:
 - (i) Transport manifests; and
 - (ii) The name and license number of all cultivators, manufacturers or dispensaries for all products sold or transferred, or purchased by the licensee for sale or transfer;
- (D) Description of each cannabis product manufactured to include product type, delta-9-tetrahydrocannabinol (delta-9-THC) content, and delta-9-tetrahydrocannabinol (delta-9-THC) potency, and any other ingredients contained in each final product;
- (E) All samples provided to a testing facility, the identity and address of the testing facility, and test results; and
- (F) A medical cannabis waste disposal log indicating the date and time, location, method of destruction, mixing medium, and agent ID(s) of the employee(s) who destroyed the cannabis product.

016. TESTING REQUIREMENTS.

016.01 REQUIRED CANNABIS AND CANNABIS PRODUCT TESTS FOR CULTIVATORS. Before the transfer of medical cannabis from a cannabis cultivation facility to a cannabis product manufacturer, the cultivation facility shall make a declaration to the Commission that the medical cannabis to be transferred is either medical cannabis or a medical cannabis cultivation byproduct.

<u>016.01(A)</u> <u>CULTIVATION BATCH TESTING.</u> A representative sample of each batch or lot of medical cannabis shall be tested by an independent cannabis testing laboratory to determine:

- (i) The water activity of the sample;
- (ii) The amount of Total THC, Delta-9-tetrahydrocannabinol (delta-9-THC) potency, Total CBD, and any THC analog known to be present in the sample; and
- (iii) The presence of adulterants in the sample, as specified in Table 1.

<u>016.01(B)</u> <u>TIME OF TESTING.</u> Required testing shall be performed either before the

transfer of the medical cannabis to a product manufacturer or following the transfer of the medical cannabis to a product manufacturer. If medical cannabis is tested before being transferred to a product manufacturer the medical cannabis shall be tested for microbial contaminants and foreign matter a second time following the transfer.

<u>016.01(C)</u> <u>MEDICAL CANNABIS BYPRODUCT.</u> Medical cannabis cultivation byproduct shall either be:

- (i) Chemically or physically processed to produce a cannabis concentrate for incorporation into cannabis derivative product; or
- (ii) Destroyed pursuant to this chapter.

<u>016.01(D)</u> <u>MEDICAL CANNABIS CONCENTRATE.</u> Medical cannabis concentrate shall be tested by an independent cannabis testing laboratory before it is incorporated into a cannabis derivative product to determine:

- (i) The cannabinoid profile; and
- (ii) The presence of adulterants in the sample, as specified in Table 1.

<u>016.02</u> <u>REQUIRED TESTING FOR PRODUCT MANUFACTURERS.</u> Before the transfer of a cannabis product to a dispensary a product manufacturer shall have a representative sample of the product tested by an independent laboratory to determine:

- (i) The water activity of the sample;
- (ii) The quantity of any cannabinoid or terpene to be listed on the product label; and
- (iii) The presence of adulterants in the sample, as specified in Table 1.

<u>016.03</u> <u>MYCOTOXIN TESTING.</u> Mycotoxin testing shall be required for medical cannabis. medical cannabis products, and medical cannabis concentrate.

<u>016.04</u> <u>REMEDIATION.</u> A cultivator or product manufacturer may remediate medical cannabis, medical cannabis concentrate, or a medical cannabis product that fails any of the required adulterant testing standards after submitting and gaining approval for a remediation plan from the Commission.

<u>016.04(A)</u> <u>REMEDIATION PLAN.</u> A remediation plan shall be submitted to the Commission within fifteen (15) calendar days of the receipt of a failed testing result.

<u>016.04(A)(i)</u> <u>RESAMPLING.</u> A remediation plan shall be carried out and the medical cannabis, medical cannabis product, or medical cannabis concentrate shall be prepared for resampling within sixty (60) calendar days of Commission approval of the remediation plan. Resampling or retesting of a cannabis lot or batch that fails any of the required testing standards is not allowed until the lot or batch has been remediated.

<u>016.04(B)</u> <u>DESTRUCTION.</u> A medical cannabis lot or medical cannabis product batch that is not or cannot be remediated in the specified time shall be destroyed in accordance with this chapter.

<u>016.05</u> <u>TESTING RESULT RETENTION.</u> If test results cannot be retained in the State Inventory Control System, the cultivator or product manufacturer shall:

- (A) Keep a record of test results:
- (B) Issue a certificate of analysis for required tests; and
- (C) Keep a copy of the certificate of analysis on the licensed premises.

TABLE 1					
	Required Test by Sample Type				
Test	Medical Cannabis				
		Concentrate	Cannabis		
			Product		
Moisture	Required	Χ	Χ		
Content	•				
Water Activity	Required	X	X		
Foreign Matter	Required	Required	Required		
Potency	Required	Required	Required		
Microbial	Required	Required	Required		
Pesticides	Required	Required	Required		
Residual	Χ	Required	Required		
Solvents					
Heavy Metals	Required	Required	Required		

<u>016.06</u> <u>SAMPLING CANNABIS PRODUCTS.</u> The registered cannabis establishment that requests testing of a medical cannabis product lot, medical cannabis concentrate batch, or medical cannabis product batch shall make the entirety of the lot or batch available to the sampling technician.

<u>016.06(A)</u> <u>SAMPLE LOCATION.</u> The lot or batch being sampled shall be contained in a single location and physically separated from other lots or batches.

<u>016.06(B)</u> <u>SAMPLING TECHNICIAN.</u> The sample shall be collected by a sampling technician who is unaffiliated with the entity that requested testing of the medical cannabis lot or medical cannabis product batch. The owner of the cannabis lot or cannabis product batch and any of their employees may not assist in the selection of the sample.

<u>016.06(C)</u> <u>REPRESENTATIVE SAMPLE.</u> In addition to the following requirements, the representative sample shall be collected in a manner that is ISO 17025 compliant and:

- (i) Collected using sterile gloves, instruments, and a glass or plastic container to collect the sample;
- (ii) Place tamper proof tape on the container; and
- (iii) Appropriately label the sample pursuant to this chapter.

<u>016.07</u> <u>SAMPLING MEDICAL CANNABIS PLANTS.</u> For medical cannabis plant lots, the minimum representative sample shall be collected according to the following schedule:

- (i) 10 subunits with an average weight of one gram each for lots weighing 5 kilograms or less;
- (ii) 16 subunits with an average weight of one gram each for lots weighing 5.01-9 kilograms;
- (iii) 22 subunits with an average weight of one gram each for lots weighing 9.01-14 kilograms:
- (iv) 28 subunits with an average weight of one gram each for lots weighing 14.01-18

- kilograms;
- (v) 32 subunits with an average weight of one gram each for lots weighing 18.01-23 kilograms.
- <u>016.08</u> <u>SAMPLING MEDICAL CANNABIS CONCENTRATE.</u> For medical cannabis concentrate, the minimum representative sample shall be collected according to the following schedule:
 - (i) 10 mL or grams for batches of one liter or kilogram or less; or
 - (ii) 20 mL or grams for batches of four liters or kilograms or less.
- <u>016.09</u> <u>SAMPLING FINAL PRODUCT.</u> For medical cannabis products in their final product form, the minimum number of sample units that must be collected, the combined total weight of which must be at least 10 grams, not including packaging materials:
 - (i) Four (4) units for a sample product batch with 5-500 products;
 - (ii) Six (6) units for a sample product batch with 501-1000 products;
 - (iii) Eight (8) units for a sample product batch with 1,001-5,000 products; and
 - (iv) Ten (10) units for a sample product batch with 5,001-10,000 products.
- <u>016.10</u> <u>ADDITIONAL MATERIAL.</u> Additional material may be included in the representative sample if the material is necessary to perform the required testing.
- 016.11 MOISTURE CONTENT TESTING AND WATER ACTIVITY STANDARDS. The moisture content of a sample and related lot of medical cannabis or medical cannabis product shall be reported on the certificate of analysis as a mass over mass percentage. A sample and related lot of medical cannabis fail quality assurance testing if the water activity of the representative sample is found to be greater than 0.65. A sample and related medical cannabis product batch intended for human consumption fail quality assurance testing if the water activity of the representative sample is greater than 0.65, unless water is a component of the product formulation and is listed as an ingredient.
- <u>016.12</u> <u>FOREIGN MATTER STANDARDS.</u> A sample and related lot or batch of medical cannabis or medical cannabis product fail quality assurance testing if:
 - (A) The sample contains foreign matter visible to the unaided human eye;
 - (B) The sample is found to contain microscopic foreign matter considered to be harmful or estimated to comprise greater than 3% of the mass of the representative sample as determined by the testing laboratory;
 - (C) Foreign matter is found that is suspected of having been intentionally added to the
 - sample to increase its visual appeal or market value; or
 - (D) For a medical cannabis product, the total number of seeds found is greater than the net weight of the sample collected divided by 1.75.
- <u>016.13 POTENCY TESTING.</u> A lot or batch of medical cannabis, medical cannabis concentrate, or medical cannabis product shall have its cannabinoid profile determined and listed on a certificate of analysis as total delta-9-tetrahydrocannabinol (delta-9-THC), Total CBD, and the total concentration of any THC analog. A lot or batch of medical cannabis, medical cannabis concentrate, or medical cannabis product fail quality assurance testing for cannabinoid content if:
 - (A) It is not analyzed for each of the analytes listed in Table 2;
 - (B) The determined amount of any analyte exceeds its action level given in Table 2;

- (C) Any tetrahydrocannabinol acetate (THC-OAc) is found in a medical cannabis concentrate with a relative peak area greater than 1% of the total cannabinoid peak area or in a medical cannabis product with a relative peak area greater than 0.5% of the total cannabinoid peak area as determined by high-performance liquid chromatography with a diode array detector;
- (D) Any synthetic or converted cannabinoids found to present as determined by highperformance liquid chromatography with a diode array detector (HPLC-DAD); or
- (E) Unknown cannabinoids consist of greater than 2% of total cannabinoid peak area as determined by high-performance liquid chromatography with a diode array detector (HPLC-DAD).

TABLE 2 Cannabinoid Components and Action Levels			
Analyte	Chemical Abstract Service	Action Level	
Δ9-Tetrahydrocannabidiol (Δ9- THC)	1972-08-03	No Limit	
Δ8-Tetrahydrocannabidiol (Δ8- THC)	5957-75-5	0.0	
Δ9-Tetrahydrocannabinolic acid (THCA)	23978-85-0	No Limit	
Δ9-Tetrahydrocannabivarin (THCV)	31262-37-0	No Limit	
Cannabidiol (CBD)	13956-29-1	No Limit	
Cannabidiolic acid (CBDA)	1244-58-2	No Limit	
Cannabidivarin (CBDV)	24274-48-4	No Limit	
Cannabinol (CBN)	521-35-7	No Limit	
Cannabigerol (CBG)	25654-31-3	No Limit	
Cannabichromene (CBC)	20675-51-8	No Limit	
Cannabigerolic acid (CBGA)	25555-57-1	No Limit	
Cannabichromenic acid (CBCA)	20408-52-0	No Limit	
9R-Δ6a,10a- Tetrahydrocannabidiol (Δ3-THC)	95720-01-7	1%1	
9S-Δ6a,10a- Tetrahydrocannabidiol (Δ3-THC)	95720-02-8	_{1%} 1	
(6aR,9R)-∆10- Tetrahydrocannabidiol	95543-62-7	1%1	

(6aR,9S)-Δ10- Tetrahydrocannabidiol	95588-87-7	1%1
Cannabicitran (CBTC)	31508-71-1	2%

¹If the laboratory performing the testing cannot chromatographically separate 9(R+S)-Δ6a,10a-Tetrahydrocannabidiol or (6aR,9(R+S))-Δ10-Tetrahydrocannabidiol, then the action level for the combined isomers will be 1.5%.

<u>016.14</u> <u>MICROBIAL STANDARDS.</u> A sample and related lot or batch of medical cannabis, medical cannabis concentrate, or medical cannabis product fail quality assurance testing for microbiological contaminants and pathogens if the results exceed the limits as set forth in Table 3. Each sample and related lot or batch shall be tested for total aerobic microbial count and total combined yeast and mold.

	TABLE 3	
Microbial Analytes and Action Levels		
Material	Microbial Limit Requirement	
	Total Aerobic Microbial Count ≤100,000 cfu/g Not detected in 1g: Salmonella spp., STEC, Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger, and Aspergillus terreus	
	Total Aerobic Microbial Count ≤10,000 cfu/g Total Combined Yeast and Mold Count ≤1,000 cfu/g Not detectable in 1g: STEC, Salmonella spp., Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger, and Aspergillus terreus	
Infused Edible Products	Total Aerobic Microbial Count ≤10,000 cfu/g Total Combined Yeast and Mold Count ≤1,000 cfu/g Not detectable in 1g: STEC, Salmonella spp.	
Infused Non- edible Products	Total Aerobic Microbial Count ≤250 cfu/g Total Yeast and Mold Count ≤250 cfu/g Not detectable in 1g: Pseudomonas aeruginosa, Staphylococcus aureus	
	Total Aerobic Microbial Count ≤10,000 cfu/g Total Combined Yeast and Mold Count ≤1,000 cfu/g Not detectable in 1 g: STEC, Salmonella spp., Pseudomonas, Staphylococcus aureus	

<u>016.15</u> <u>PESTICIDE STANDARDS.</u> Only pesticides allowed by this chapter may be used in the cultivation of medical cannabis. If an independent cannabis laboratory identifies a pesticide that is above the action levels as set forth in Table 4 and this chapter, that lot or batch from which the sample was taken has failed quality assurance testing. The following provisions

apply to pesticide testing:

- (A) Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774- 45-7 and 51877-74-8);
- (B) Pyrethrins should be measured as the cumulative residues of pyrethrin I (CAS 121-21-1), pyrethrin II (CAS 121- 29-9), cinerin 1 (CAS 25402-06-6), and jasmolin 1 (CAS 4466-14-2); and
- (C) Abamectin is a composite of the amounts of avermectin B1a and avermectin B1b.

	TABLE 4			
Pesticide Analytes and Action Levels				
Analyte	Chemical Abstract	Action Level		
	Service (CAS)	ppm		
	Registry number			
Abamectin	71751-41-2	0.15		
Acephate	30560-19-1	0.4		
Acequinocyl	57960-19-7	2.0		
Acetamiprid	135410-20-7	0.2		
Aldicarb	116-06-3	0.4		
Azoxystrobin	131860-33-8	0.2		
Bifenazate	149877-41-8	0.2		
Bifenthrin	82657-04-3	0.2		
Boscalid	188425-85-6	0.4		
Carbaryl	63-25-2	0.2		
Carbofuran	1563-66-2	0.2		
Chlorantranilipro	500008-45-7	0.2		
le				
Chlorfenapyr	122453-73-0	1.0		
Chlorpyrifos	2921-88-2	0.2		
Clofentezine	74115-24-5	0.2		
Cyfluthrin	68359-37-5	<u> </u> 1		
Cypermethrin	52315-07-8	1		
Daminozide	1596-84-5	1		
DDVP	62-73-7	0.1		
(Dichlorvos)				
Diazinon	333-41-5	0.2		
Dimethoate	60-51-5	0.2		
Ethoprophos	13194-48-4	0.2		
Etofenprox	80844-07-1	0.4		
Etoxazole	153233-91-1	0.1		
Fenoxycarb	72490-01-8	0.2		
Fenpyroximate	134098-61-6	0.4		
Fipronil	120068-37-3	0.4		
Flonicamid	158062-67-0	1		
Fludioxonil	131341-86-1	0.4		
Hexythiazox	78587-05-0	1		
lmazalil	35554-44-0	0.1		
Imidacloprid	138261-41-3	0.4		



Kresoxim-	143390-89-0	0.4	
methyl			
Malathion	143390-89-0	0.2	
Metalaxyl	57837-19-1	0.2	
Methiocarb	2032-65-7	0.2	
Methomyl	16752-77-5	0.1	
Methyl parathior	n 298-00-0	0.2	
MGK-264	113-48-4	0.2	
Myclobutanil	88671-89-0	0.2	
Naled	300-76-5	0.5	
Oxamyl	23135-22-0	1	
Paclobutrazol	76738-62-0	0.4	
Permethrins	52645-53-1	0.2	
Phosmet	732-11-6	0.2	
Piperonyl_butox	ii <mark>51-03-6</mark>	2	
de			
Prallethrin	23031-36-9	0.2	
Propiconazole	60207-90-1	0.4	
Propoxur	114-26-1	0.2	
Pyrethrins	8003-34-7	1	
Pyridaben	96489-71-3	0.2	
Spinosad	168316-95-8	0.2	
Spiromesifen	283594-90-1	0.2	
Spirotetramat	203313-25-1	0.2	
Spiroxamine	118134-30-8	0.4	
Tebuconazole	80443-41-0	0.4	
Thiacloprid	111988-49-9	0.2	
Thiamethoxam	153719-23-4	0.2	
Trifloxystrobin	141517-21-7	0.2	

016.16 RESIDUAL SOLVENT STANDARDS. A sample and related lot or batch of medical cannabis, medical cannabis concentrate, or medical cannabis product fails quality assurance testing for residual solvents if the results exceed the limits provided in Table 5 unless the solvent is:

- (i) A component of the product formulation;
- (ii) Listed as an ingredient; and
- (iii) Generally considered to be safe for the intended form of use.

016.16(A) XYLENES. Xylenes is a combination of the following:

- (i) 1,2-dimethylbenzene;(ii) 1,3-dimethylbenzene;
- (iii) 1,4-dimethylbenzene; and
- (iv) ethyl benzene.

TABLE 5				
List of Solvents and Action Levels				
Solvent	Chemical Abstract	Action		
	Service (CAS)	level ppm		
	Registry number			
1,2	110-71-4	100		
Dimethoxyethane				
1,4 Dioxane	123-9	380		
1-Butanol	71-36-3	5,000		
1-Pentanol	71-41-0	5,000		
1-Propanol	71-23-8	5,000		
2-Butanol	78-92-2	5,000		
2-Butanone	78-93-3	5,000		
2-Ethoxyethanol	110-80-5	160		
2-methylbutane	78-78-4	5,000		
2-Propanol (IPA)	67-63-0	5,000		
Acetone	67-64-1	1,000		
Acetonitrile	75-05-8	410		
	71-43-2	2		
Benzene Butano	106-97-8			
Butane		1,000 70		
Cumene	98-82-8			
Cyclohexane	110-82-7	3,880		
Dichloromethane	75-09-2	600		
2,2-dimethylbutane	75-83-2	290		
2,3-dimethylbutane	79-29-8	290		
1,2-	95-47-6	See		
dimethylbenzene	400.00.0	Xylenes		
1,3-	108-38-3	See		
dimethylbenzene	400 40 0	Xylenes		
1,4-	106-42-3	See		
dimethylbenzene	07.00.5	Xylenes		
Dimethyl sulfoxide	67-68-5	5,000		
Ethanol	64-17-5	1,000		
Ethyl acetate	141-78-6	1,000		
Ethylbenzene	100-41-4	See		
	00.00.7	Xylenes		
Ethyl ether	60-29-7	1,000		
Ethylene glycol	107-21-1	620		
Ethylene Oxide	75-21-8	50		
Heptane	142-82-5	1,000		
n-Hexane	110-54-3	60		
Isopropyl acetate	290	5,000		
Methanol	67-56-1	600		
Methylpropane	75-28-5	5,000		
2-Methylpentane	107-83-5	290		

3-Methylpentane	96-14-0	290
N,N-	127-19-5	1,090
dimethylacetamide		
N,N-	68-12-2	880
dimethylformamide		
Pentane	109-66-0	1,000
Propane	74-98-6	1,000
Pyridine	110-86-1	100
Sulfolane	126-33-0	160
Tetrahydrofuran	109-99-9	720
Toluene	108-88-3	80
Xylenes	1330-20-7	430

<u>016.17 HEAVY METAL STANDARDS.</u> A sample and related lot or batch of medical cannabis, medical cannabis concentrate, or medical cannabis product fail quality assurance testing for heavy metals if the results exceed the limits provided in Table 6.

TABLE 6		
Heavy N	Metals	
Metals	Natural Health	
	Products	
	Acceptable limits	
	in parts per	
	million	
Arsenic	<.2 inhaled	
	<.4 non-inhaled	
Cadmium	<0.2	
Lead	<.5	
Mercury	<0.4	

<u>016.18 MYCOTOXIN STANDARDS.</u> A sample and related lot or batch of medical cannabis, medical cannabis concentrate, or medical cannabis product fail quality assurance testing for mycotoxin if the results exceed the limits provided in Table 7.

TABLE 7		
Mycotoxir	1	
Test	Specification	
The Total of		
Aflatoxin B1,		
Aflatoxin B2,		
Aflatoxin G1,		
and		
Aflatoxin G2	<20 ppb of	
	substance	
Ochratoxin A.	<20 ppb of	
	substance	

017. TRANSPORTER REQUIREMENTS.

- <u>017.01</u> <u>POSSESSION FOR TRANSPORTING.</u> A transporter may only possess or transport cannabis for medical purposes, as defined by Neb. Rev. Stat. § 71-24,107, and those purposes expressed in this chapter.
- <u>017.02</u> <u>TRANSPORTING FOR SALE OR TRANSFER.</u> A transporter may only transport, possess cannabis for transport to a licensed dispensary, a licensed product manufacturer, a licensed cultivator, or another licensed transporter.
- <u>017.03</u> <u>LOCATION.</u> All storage of medical cannabis for transportation shall take place at the premise identified in the transporter license.
- <u>017.04</u> <u>LOCATION ACCESS.</u> Transportation storage locations must be secured to reasonably prevent access to any cannabis plants or products by animals, or individuals who are not authorized agents of the manufacturer or otherwise authorized access by law.
- O17.05 CANNABIS SEED, CANNABIS PLANT STOCK OR CANNABIS PRODUCT. A transporter may only obtain cannabis seeds, cannabis plants, or cannabis products from a Nebraska licensed cultivator, Nebraska licensed product manufacturer, Nebraska licensed dispensary or another Nebraska licensed transporter, or a cannabis cultivator authorized to operate in another State of the United States.
- <u>017.06</u> <u>ALLOWABLE PRODUCTS.</u> A transporter may only transport cannabis for medical purposes or cannabis products allowed to be sold or transferred under this chapter or the Nebraska Cannabis Regulation Act.
- <u>017.07</u> <u>PACKAGING.</u> Transporters may only sell or transfer products that are sealed and comport with the following:
 - (A) The package shall protect the product from contamination and shall not expose the product to any toxic or harmful substance; and
 - (B) The package shall be tamper-evident, which means the product shall be packaged in a container within which a product is sealed so that the contents cannot be opened without obvious destruction of the seal.
- <u>017.08</u> <u>POSSESSION.</u> A transporter is responsible for the cannabis, cannabis products, and cannabis accessories once taking possession.
- <u>017.09</u> <u>STORAGE.</u> A transporter may maintain storage facilities at the premises identified in the transporter's license for temporary storage of cannabis, cannabis products, and cannabis accessories.
- <u>017.10</u> <u>MANIFEST REQUIREMENTS.</u> A manifest is required for all cannabis for medical purposes transported. A manifest shall contain the following information:
 - (A) The date the manifest was created;
 - (B) The license number, address, and contact information of the originating registered cannabis establishment;
 - (C) The license number, address, and contact information of the receiving registered cannabis establishment;
 - (D) The quantity, by weight and unit and product type, of the cannabis for medical purposes being transports;

- (E) The name of each person accompanying the transport;
- (F) The date and time of departure and delivery;
- (G) The transport driver's signature once the delivery has been completed; and
- (H) The name and signature of the authorized agent of the receiving registered cannabis establishment confirming receipt of the cannabis for medical purposes.
- <u>017.11</u> <u>MANIFEST COPIES.</u> A transporter is required to provide a copy of each manifest to the originating party and the receiving party.
- <u>017.12</u> <u>VEHICLES PERMITTED.</u> Vehicles permitted to transport cannabis for medical purposes must:
 - (A) Be equipped with a locked storage compartment or container;
 - (B) Have no markings that would either identify or indicate the vehicle is being used to transport cannabis for medical purposes;
 - (C) Carry a copy of the valid transporter license for the registered cannabis establishment that is the registered owner of the vehicle; and
 - (D) Meet the Nebraska requirements to be operated lawfully on public roads.

017.13 DRIVER REQUIREMENTS. A transport driver must:

- (A) Have a means of communication to allow contact with the originating or receiving registered cannabis establishment or 911;
- (B) Conspicuously display an employee identification badge issued by the licensed transporter;
- (C) Possess a valid Nebraska driver's license; and
- (D) Not wear any clothing which would indicate possession of medical cannabis.

<u>017.14</u> <u>RECORDS REQUIRED FOR TRANSPORTERS.</u> Transporters must retain the following records for no less than seven (7) years:

- (A) Invoices or receipts for all transports of cannabis for medical purposes, which shall include the following:
 - (i) Name and address of each receiver, originator and payor;
 - (ii) Date of sale and invoice number;
 - (iii) Item, category, and quantity of cannabis product transported or stored;
 - (iv) The cost to the payor, together with any discount applied to the price as shown on the invoice:
 - (v) Transporters name, license number and address;
- (B) Daily inventory records which shall include the following;
 - (i) The type, quantity of all medical cannabis products stored or transported;
 - (ii) Daily transactions; and
 - (iii) Any discrepancies between the daily inventory and daily transactions; and
- (C) Records of all transports which include:
 - (i) Transport manifests; and
 - (ii) The name and license number of all cultivators, manufacturers or dispensaries for all products stored or transported, or purchased by the licensee for transport or storage.

018. LABELING AND PACKAGING REQUIREMENTS.

<u>018.01</u> <u>LABEL TEXT SIZE.</u> Labeling text on container must be unobstructed and conspicuous. The labeling text on the container must be no smaller than ten (10) point font.

<u>018.02</u> <u>PACKAGING LABEL NECESSARY INFORMATION.</u> The label for a medical cannabis product shall include an information panel that includes only the following:

- (A) The licensed manufacturer and its contact number or website address;
- (B) The date of manufacture and expiration date; and
- (C) Each of the following statements:
 - (i) "SCHEDULE I CONTROLLED SUBSTANCE";
 - (ii) "KEEP OUT OF REACH OF CHILDREN AND ANIMALS";
 - (iii) "FOR MEDICAL USE BY QUALIFIED PATIENTS ONLY";
 - (iv) "THE INTOXICATING EFFECTS OF THIS PRODUCT MAY BE DELAYED";
 - (v) "THIS PRODUCT MAY IMPAIR THE ABILITY TO DRIVE OR OPERATE MACHINERY, PLEASE USE EXTREME CAUTION":
 - (vi) "IT IS ILLEGAL TO TRANSFER MEDICAL CANNABIS TO ANOTHER PERSON:"
 - (vii) "CONSUMPTION OF TETRAHYDROCANNABINOL (THC) AND ANY FORM OF MEDICAL CANNABIS DURING PREGNANCY CAN CAUSE BIRTH DEFECTS;"
 - (viii) "CONSUMPTION OF TETRAHYDROCANNABINOL (THC) AND ANY FORM OF MEDICAL CANNABIS CAN IMPAIR YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY;" and
 - (ix) "CONSUMPTION OF TETRAHYDROCANNABINOL (THC) AND ANY FORM OF MEDICAL CANNABIS MAY CAUSE HEALTH PROBLEMS, INCLUDING PSYCHOSIS."

<u>018.03</u> <u>ADDITIONAL INFORMATION REQUIRED TO BE PROVIDED.</u> Qualified patients or caregivers must be provided with the following information with each quantity of cannabis dispensed:

- (A) A list of all product ingredients in descending order of predominance by weight or volume:
- (B) The batch or lot number;
- (C) Instructions for intake, such as method consumption or application, and any preparation necessary prior to use;
- (D) The amount of delta-9-tetrahydrocannabinol (delta-9-THC) in mg per dose and per container;
- (E) The delta-9-tetrahydrocannabinol (delta-9-THC) potency of the product;
- (F) The unique manufacturer license number and unique registration number for the product; and
- (G) A notice that adverse events may be reported to the dispensary and the method and contact information for reporting to the dispensary.

<u>018.04</u> <u>PACKAGING REQUIREMENTS.</u> A package used to contain a cannabis product shall adhere to the following requirements:

- (A) The package shall protect the product from contamination and shall not expose the product to any toxic or harmful substance;
- (B) The package shall be tamper-evident, which means the product shall be packaged in a container within which a product is sealed so that the contents cannot be opened without obvious destruction of the seal;
- (C) The package shall be child-resistant, which means the package shall be designated or constructed to be significantly difficult for children under five (5) years of age to open or otherwise obtain access to the product contained therein within a reasonable time and shall not be difficult for normal adults to open or obtain access to the product contained therein. A package shall be deemed child-resistant if it satisfies the

- standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 regulations (16 CFR § 1700(b)(4)); and
- (D) The package shall be resealable, which means the package continues to function within effectiveness specifications set forth in the Poison Prevention Packaging Act of 1970 regulations for the number of opening and closings customary for its size and contents.

<u>018.05</u> <u>LABELING PLACEMENT.</u> Product packaging may not be designed in such a manner that the required elements for packaging and labeling are easily removed or separated from the package, such as placing required information on part of the package that must be removed to access the product.

<u>018.06</u> <u>PROHIBITED PACKAGING.</u> The product's container, labeling, or packaging shall not contain any of the following:

- (A) Depictions of cartoon-like fictional characters that mimic a character primarily aimed at entertaining minors;
- (B) Trademarks or trade dress of products that imitate or mimic those of products that are or have been primarily marketed to minors;
- (C) Symbols that are primarily used to market products to minors;
- (D) Images or likenesses of celebrities; or
- (E) Any packaging or labeling which otherwise violates any state or federal law or trademark.

019. RECOMMENDING HEALTH CARE PRACTITIONER DIRECTORY.

<u>019.01</u> <u>RECOMMENDING HEALTH CARE PRACTITIONER.</u> In order to submit written orders to a Nebraska licensed dispensary, a recommending health care practitioner must enroll in the Recommending Health Care Practitioner Directory as established by the Commission, if the practitioner meets the requirements of this chapter. Only health care practitioners who primarily practice medicine in Nebraska may be enrolled.

<u>019.01(A)</u> <u>ENROLLMENT INFORMATION.</u> A health care practitioner must supply the following information when enrolling in the Directory:

- (i) Name;
- (ii) Health care practitioner license number;
- (iii) Work address;
- (iv) Health care practitioner type; and
- (v) An attestation of education requirement completion as required by this section.

<u>019.01(B)</u> <u>ENROLLMENT RENEWAL.</u> A health care practitioner enrolled in the Recommending Health Care Practitioner Directory must re-enroll annually by submitting the enrollment and education information required by this chapter at least thirty (30) days prior to their current enrollment's expiration date, but no sooner than ninety (90) days prior to the expiration date.

<u>019.02</u> <u>EDUCATION REQUIREMENTS.</u> Prior to enrolling in the Recommending Health Care Practitioner Directory, the health care practitioner must complete ten hours of accredited courses related to medical cannabis. To maintain enrollment in the Directory, the health care practitioner must complete, at a minimum, an annual accredited two-hour refresher course related to medical cannabis. Courses must be accredited by the Accreditation Council for Continuing Medical Education.

<u>019.03</u> <u>ELECTRONIC DELIVERY REQUIREMENT.</u> Enrolled health care practitioners must send written recommendations and written orders to dispensaries utilizing the dispensary's established electronic delivery system and submit electronic copies of written recommendations and written orders to the Commission in the manner prescribed by the Commission.

<u>019.04</u> <u>RESTRICTIONS.</u> A health care practitioner enrolled in the Directory shall not:

- (A) Accept, solicit, or offer any form of pecuniary remuneration from or to any person licensed under the Nebraska Medical Cannabis Regulation Act;
- (B) Accept, solicit, or offer any form of pecuniary renumeration from or to any caregiver, except that this subdivision shall not prohibit payment to a practitioner by a caregiver who is paying the practitioner for services provided to a qualified patient;
- (C) Offer a discount or any other thing of value to a qualified patient who uses or agrees to use a particular dispensary or caregiver;
- (D) Be located at the same physical address as a dispensary;
- (E) Advertise for any registered cannabis establishment;
- (F) Hold an economic interest in any entity licensed under the Nebraska Medical Cannabis Regulation Act;
- (G) Electronically deliver the same written order for the same qualified patient to more than one dispensary;
- (H) Electronically deliver more than one written order for the same qualified patient within thirty (30) days; or
- (I) Provide a written order for a patient if the health care practitioner did not provide the patient's written recommendation.

<u>019.05</u> <u>RECORD RETENTION.</u> A health care practitioner enrolled in the Directory that sends a written recommendation or written order to a dispensary must retain records of each written recommendation or written order for no less than seven (7) years.

<u>019.06</u> <u>DISENROLLMENT.</u> The Commission may disenroll a health care practitioner who fails to comply with the requirements of this chapter.

020. STATE INVENTORY TRACKING SYSTEM.

O20.01 STATE INVENTORY TRACKING SYSTEM PARTICIPATION. Upon implementation of the state inventory tracking system, no registered cannabis establishment shall sell or otherwise transfer, purchase, obtain or otherwise accept the transfer of medical cannabis or otherwise accept the transfer of medical cannabis or medical cannabis products that are not properly inputted and tracked in the state inventory tracking system. Each registered cannabis establishment shall use the state inventory tracking system by inputting inventory tracking data required to be reported to the Commission directly into the state inventory tracking system. All registered cannabis establishments must have an inventory tracking system account activated to lawfully operate and must ensure all information is reported to the Commission accurately and in real time or after each individual sale. Registered cannabis establishments shall ensure the following information and data are accurately tracked and timely reported to the Commission through the state inventory tracking system:

(A) The chain of custody of all medical cannabis and medical cannabis products, including every transaction with another registered cannabis establishment, which includes:

- (i) The name, address, license number, and phone number of the registered cannabis establishment that cultivated, manufactured, sold, purchased, or otherwise transferred the medical cannabis or medical cannabis product(s);
- (ii) The type, item, strain, and category of medical cannabis or medical cannabis product(s) involved in the transaction;
- (iii) The weight, quantity, delta-9-tetrahydrocannabinol (delta-9-THC) content, delta-9-tetrahydrocannabinol (delta-9-THC) potency, and directions for use of the medical cannabis or medical cannabis product(s) involved in the transaction;
- (iv) The batch number of the medical cannabis or medical cannabis product(s);
- (v) The total amount spent in dollars;
- (vi) All point-of-sale records as applicable;
- (vii) All inventory manifests and other documentation relating to the transport of medical cannabis or medical cannabis products as required by this chapter;
- (viii) Testing results and information;
- (ix) Waste records and information;
- (x) Applicable sales or excise tax records;
- (xi) Inventory tracking system tag number(s); and
- (xii) Any other information as required by this chapter; and
- (B) The entire life span of a registered cannabis establishment's stock of medical cannabis and medical cannabis products, including, at a minimum, notifying the Commission:
 - (i) When medical cannabis seeds or clones are planted;
 - (ii) When medical cannabis plants are harvested or destroyed;
 - (iii) When medical cannabis is transported, or otherwise transferred, sold, stolen, diverted, or lost;
 - (iv) When medical cannabis changes form, including, when it is planted, cultivated, processed, and infused or otherwise processed into a final product;
 - (v) A complete inventory of all medical cannabis, seeds, plant tissue, clones, usable medical cannabis, trim, shake, leaves, other plant matter, and medical cannabis products;
 - (vi) All samples sent to a testing laboratory or used for internal quality testing or other purposes; and
 - (vii) Any other information as required by this chapter.

<u>REGISTERED</u> CANNABIS ESTABLISHMENT INVENTORY TRACKING REQUIREMENTS. Upon implementation of the state inventory tracking system, each registered cannabis establishment shall track, update, and report inventory in the state inventory tracking system after each individual sale. Registered cannabis establishments must ensure all on-premises and in-transit medical cannabis and medical cannabis product inventories are reconciled each day in the state inventory tracking system at the close of business.

<u>020.03</u> <u>INVENTORY TRACKING SYSTEM TAGS.</u> Registered cannabis establishments are required to use inventory tracking system tags from a Commission-approved supplier for the state inventory tracking system. Each establishment is responsible for the cost of all inventory tracking system tags and any associated vendor fees. A registered cannabis establishment shall ensure an adequate supply of inventory tracking system tags at all times.

<u>020.03(A)</u> <u>INVENTORY DESIGNATIONS.</u> Registered cannabis establishments shall designate inventory as either medical cannabis, medical cannabis products, or medical cannabis waste.

<u>020.03(B)</u> <u>UNACCOUNTED FOR INVENTORY TAGS.</u> If a registered cannabis establishment is unable to account for unused inventory tracking system tags, the establishment must report to the Commission and the state inventory tracking system vendor within forty-eight (48) hours.

<u>020.03(C) INVENTORY TAG REQUIREMENTS.</u> Inventory tracking tags must contain the legal name and correct license number of the establishment that ordered them. Registered cannabis establishments are prohibited from using another establishment's inventory tracking system tags.

020.03(D) INVENTORY TRACKING TAG PLACEMENT. The inventory tracking system tag shall be placed on the container holding the medical cannabis plant and must remain physically near and clearly associated with the medical cannabis plant until the plant reaches twelve (12) inches in height. Clones must be tracked in the state inventory tracking system and must be associated with a wholesale package tag, whether cut from a mother plant or transferred from another licensee, prior to reaching twelve (12) inches in height. When the plant reaches twelve (12) inches in height, the inventory tracking system tag shall be securely fastened to a lower supporting branch. The inventory tracking system tag shall remain affixed for the entire life of the plant until disposal. If the plant changes forms, is removed from the original planting location after harvest, or is being trimmed, dried, or cured by the grower, the inventory tracking system tag shall be placed on the container holding the medical cannabis plants and/or must remain physically near and clearly associated with the medical cannabis plants until the plant is placed into a package in both the state inventory tracking system and physically packaged and affixed with the inventory tracking system tag.

<u>020.03(E)</u> <u>TAGGED MOTHER PLANTS.</u> Mother plants must be tagged before any cuttings or clones are generated therefrom.

<u>020.03(F)</u> <u>WHOLESALE INVENTORY TAGS.</u> Each wholesale package of medical cannabis must have an inventory tracking system tag during storage and transfer and may only contain one harvest batch of medical cannabis.

<u>020.03(G)</u> TRANSFER OF IMMATURE PLANTS. Prior to transfer, registered cannabis establishments shall ensure that each immature plant is properly affixed with an inventory tracking system tag if the plant was not previously tagged in accordance with this chapter.

<u>020.03(H)</u> <u>STORAGE AND TRANSFER.</u> Registered cannabis establishments must affix an inventory tracking system tag to all medical cannabis products during storage and transfer in one of the following manners:

- (i) Individual units of medical cannabis products shall each be affixed with an inventory tracking system tag; or
- (ii) Medical cannabis products combined in a single wholesale package may be affixed with one inventory tracking system tag only if all units are from the same production batch. If any medical cannabis or medical cannabis products are removed from a wholesale package, each individual unit or new wholesale package must be separately tagged.

<u>020.03(I)</u> <u>WASTE.</u> All packages of medical cannabis waste shall have an inventory tracking system tag affixed and the contents of the waste package shall be reported in the state inventory tracking system.

<u>020.03(J)</u> <u>REPLACEMENT INVENTORY TAGS.</u> If an inventory tracking system tag gets destroyed, stolen, or falls off of a medical cannabis plant or medical cannabis product, the registered cannabis establishment must affix a new inventory tracking system tag on the medical cannabis plant or medical cannabis product and document the change in the state inventory tracking system.

<u>020.03(K)</u> <u>INVENTORY TAG REUSE.</u> Registered cannabis establishments shall not reuse any inventory tracking system tag previously affixed to any regulated medical cannabis or medical cannabis products.

<u>020.04</u> <u>INVENTORY TRACKING SYSTEM ADMINISTRATORS AND USERS.</u> Each registered cannabis establishment must designate at least one inventory tracking system administrator who must attend and complete all required inventory tracking system training provided by the state inventory tracking system vendor. Each registered cannabis establishment must have at least one owner, or manager, who is an inventory tracking system administrator. If the designated inventory tracking system administrator changes, the establishment shall assign a new administrator within thirty (30) calendar days.

<u>020.04(A)</u> <u>USER LIST.</u> Registered cannabis establishments shall maintain an accurate and complete list of all inventory tracking system administrators and employee users.

<u>020.04(B)</u> TRAINING REQUIREMENT. All owners and employees granted inventory tracking system account access for the purpose of conducting inventory tracking functions must be trained and authorized by the registered cannabis establishment before accessing the state inventory tracking system.

<u>020.04(C)</u> <u>ACCOUNT USAGE.</u> All inventory tracking system users shall be assigned an individual account in the state inventory tracking system. Any individual entering data into the state inventory tracking system shall only use the inventory tracking system account assigned specifically to that individual. Each inventory tracking system administrator and inventory tracking system user must have unique log-in credentials that shall not be used by any other person.

<u>020.04(D)</u> <u>ACCOUNT ACCESS TERMINATION.</u> Registered cannabis establishments shall terminate access within three (3) business days for any inventory tracking system administrator or user individual who no longer utilizes the state inventory tracking system.

<u>020.05 STATE INVENTORY TRACKING SYSTEM AVAILABILITY.</u> If at any time a registered cannabis establishment loses access to the state inventory tracking system due to circumstances beyond the establishment's control, the establishment shall keep and maintain records detailing all inventory tracking activities that were conducted during the loss of access. Once access is restored, all inventory tracking activities that occurred during the loss of access must be immediately entered into the state inventory tracking system. If an establishment loses access to the state inventory tracking system due to circumstances within its control, the establishment may not perform any business activities that would be required to be reported into the state inventory tracking system until access is restored and reporting is resumed.

- <u>020.06</u> <u>STATE INVENTORY TRACKING SYSTEM ACCESS</u>. Only registered cannabis establishments and the Commission may access the state inventory tracking system. Law enforcement agents may request access to the state inventory tracking system, which the Commission may provide at its discretion. Each registered establishment is responsible for the cost of participating in the state inventory tracking system.
- <u>020.07</u> <u>CONFIDENTIALITY.</u> All information in the state inventory tracking system is confidential to the extent allowed by law.

021. COMMISSION.

- <u>021.01</u> <u>MAJORITY.</u> A majority the appointed Commission members shall constitute a quorum. Every act of the majority shall be deemed to be an act of the Commission.
- <u>021.02</u> <u>EMPLOYEES.</u> The Commission may appoint or employ the staff necessary to carry out the Nebraska Medical Cannabis Regulation Act or to perform the duties and exercise the powers of the Commission.
- <u>021.03</u> <u>INVESTIGATION POWERS.</u> The Commission may, on its own motion or on complaint, investigate registered cannabis establishments for any violation of this chapter or the Nebraska Medical Cannabis Regulation Act.
 - <u>021.03(A)</u> <u>ON-SITE INSPECTION.</u> The Commission or its employees may enter onto a licensed premises or transporter vehicle with or without notice for the purposes of enforcing or investigating compliance with this chapter of the Nebraska Medical Cannabis Regulation Act.
 - <u>021.03(B)</u> <u>RECORD INSPECTION.</u> The Commission or its employees may request copies of or view the originals of any record required to be kept by this chapter or the Nebraska Medical Cannabis Regulation Act.
 - <u>021.03(C)</u> <u>REFUSAL OR OBSTRUCTION.</u> Registered establishments must comply with all requests made by the Commission or its employees to investigate compliance with this chapter or the Nebraska Medical Cannabis Regulation Act. Obstructing an investigation or refusal to comply with any such request may result in sanctions including immediate license revocation.