



MARIJUANA MANUFACTURING FACILITIES

**Maine Medical Use of Marijuana Program
Office of Marijuana Policy
Department of Administrative and Financial Services**

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General

The activities described in this rule may be considered a violation of federal law. Persons cultivating, manufacturing, testing, selling, purchasing or otherwise receiving medical marijuana, marijuana products, or marijuana concentrate may be subject to federal sanctions for what may otherwise be considered authorized conduct in the State of Maine, and compliance with the rule does not exempt registrants, their assistants, employees, or patients from possible federal prosecution. The Department is not responsible or liable for the actions of registered caregivers, dispensaries, manufacturing facilities, or inherently hazardous extraction facilities under the rule.

Section 1 – Administration

1.1 – Purpose and Scope

This rule is promulgated to establish standards and procedures related to manufacturing marijuana, marijuana concentrate, and marijuana products. This rule implements requirements of 22 MRS, chapter 558-C, including a marijuana track and trace system, and establishes minimum standards for manufacturing marijuana and marijuana products for medical use, including requirements for facility registration, requirements for engaging in marijuana extraction using inherently hazardous substances, staff qualifications, and security and testing. This rule protects public health and assures safe practices related to marijuana manufacturing, requiring a level of competency of facility personnel and appropriate equipment to process and extract marijuana. This rule establishes the form and content of initial and renewal applications for certification. This rule is in addition to the requirements of 10-144 *Code of Maine Rules* (“CMR”), chapter 122, *Maine Medical Use of Marijuana Program Rule*. In case of any inconsistencies between this rule and Chapter 122, this rule controls. (*APA Office Note: 10-144 chapter 122 has been relocated to 18-691 chapter 2.*)

1.2 – Authority

22 MRS, chapter 558-C.

1.3 – Definitions

For the purposes of this rule, the definitions included in this rule are in addition to the definitions contained in 22 MRS, chapter 558-C; unless the context otherwise indicates, the following terms have the following meanings:

1. **Audit** means a systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management and reporting aspects of a system to determine whether quality assurance, quality control and technical activities are being conducted as planned. An audit is conducted to determine whether these activities will effectively achieve quality objectives.
2. **Act** means the *Maine Medical Use of Marijuana Act*.
3. **Assistant** means a person paid to perform a service for a caregiver, dispensary, manufacturing facility or marijuana testing facility, whether as an employee or independent contractor, whose services include direct or indirect contact with marijuana or marijuana products.
4. **Cannabidiol (CBD)** is Chemical Abstracts Service number 13956-29-1.
5. **Certificate of analysis** means the document prepared by a testing facility that documents the analytical testing performed and results produced by the testing laboratory for a specific marijuana sample or product.

6. **Department** means the Department of Administrative and Financial Services.
7. **Exempt caregiver** means a natural person who is a caregiver for no more than two family members or members of the caregiver's household, is exempt from registration pursuant to 22 MRS §2423-A(3)(C) and may not possess more than 8 pounds of marijuana.
8. **Extraction** means a process of extracting marijuana concentrate from marijuana using water, lipids, gases, solvents or other chemicals or chemical processes. The use of inherently hazardous substances in marijuana extraction is restricted by this rule.
9. **Harvested marijuana** means plant material harvested from a mature marijuana plant, except the stalk, leaves and roots of the plant that are not used for a qualifying patient's medical use. Harvested marijuana includes marijuana concentrate and marijuana products.
10. **Homogeneous** means manufactured in a manner that results in the amount of marijuana or marijuana concentrate and cannabinoids within the product being consistent and reasonably equally dispersed throughout the product or throughout each portion of the product or concentrate; or a sample representative of the whole.
11. **Inherently hazardous substance** ("IHS") means a liquid chemical; a compressed gas; carbon dioxide (CO₂); or a commercial product that has a flash point at or lower than 38 degrees Celsius or 100 degrees Fahrenheit, including, but not limited to, butane, propane and diethyl ether. For the purposes of this Rule, inherently hazardous substances include the potentially hazardous extraction methods listed at Section 4.1.2(B) and excludes any form of alcohol or ethanol. A person or entity extracting marijuana is authorized to use only inherently hazardous substances approved by this rule.
12. **Inherently hazardous substance registration** means a valid registration issued by the Department authorizing a tier 1 or tier 2 manufacturing facility, patient, caregiver, dispensary, or freestanding entity to engage in extraction using the inherently hazardous substances approved by the Department only and that do not exceed thresholds established for required testing.
13. **Local authorization** means authorization from a municipality in accordance with 22 MRS §2429-D.
14. **Manifest form** means a record, either paper or electronic, required by the Department for a registered caregiver, dispensary, or licensed facility to document the possession and transfer of the marijuana or marijuana product on the premises, tracking all inventory, acquisition, sales and waste disposal.
15. **Manufacturing facility** means a registered tier 1 or tier 2 manufacturing facility or a person or entity authorized to engage in marijuana extraction using IHS under 22 MRS §2423-F.
16. **Manufacture or manufacturing** means the production, blending, infusing, compounding or other preparation of marijuana concentrate and marijuana products by a registered manufacturing facility, or by a patient, caregiver or dispensary as authorized under 22 MRS, chapter 558-C. Manufacturing includes, but is not limited to, marijuana extraction or preparation by means of chemical synthesis. "Manufacturing or manufacture" does not include cultivation.
17. **Marijuana concentrate** means the resin extracted from any part of a marijuana plant and every compound, manufacture, salt, derivative, mixture or preparation from such resin, including, but not limited to hashish.
18. **Marijuana** means the leaves, stems, flowers and seeds of all species of the plant genus Cannabis, whether growing or not, used for medical purposes and conduct authorized under 22 MRS, chapter 558-C.
19. **Marijuana product** means a product composed of marijuana, or marijuana concentrate and other ingredients that is intended for medical use. "Marijuana product" includes, but is not limited to, an edible marijuana product, a marijuana inhalant, a marijuana ointment and a marijuana tincture. "Marijuana product" does not include marijuana concentrate.

20. **Marijuana testing facility** means an entity licensed by the Department and certified to test medical use marijuana, including concentrates and products containing marijuana, for research and development purposes and to analyze contaminants in, and the potency and cannabinoid profile of, marijuana samples and products containing marijuana cultivated in accordance with 22 MRS, chapter 558-C.
21. **Patient** means a qualifying patient, or a visiting qualifying patient, who is 18 years of age or older, and possesses a valid written certification for the medical use of marijuana obtained pursuant to 22 MRS §2423-B or a valid out-of-state credential for the medical use of marijuana pursuant to 22 MRS §2423-D.
22. **Person** means any individual, firm, partnership, joint venture, association, corporation, limited liability company, estate, trust, business trust, receiver, syndicate, or any other group or combination acting as a unit, and the plural as well as the singular.
23. **Premises** means the structure or structures and land specified in the application for registration that is owned, leased, or otherwise held under the control of the applicant or registrant where conduct related to marijuana manufacturing takes place. The premises must be a contiguous area and may only be occupied by one registrant, unless otherwise permitted by statute and this rule.
24. **Registration certificate** means a document containing a unique registry identification number that permits the manufacturing of marijuana and marijuana products for medical use.
25. **Registry identification card** means a photographic identification card issued by the Department to an individual who is authorized to manufacture marijuana or marijuana products for medical use, in the capacity of or in the employ of a patient, caregiver, dispensary or manufacturing facility. For the purposes of these rules, the Department may issue a registry identification card to any person who holds an active and valid Individual Identification Card issued under Maine's Adult Use Marijuana Program authorized by 28-B MRS, chapter 1.
26. **Sample** means a portion of marijuana or marijuana product containing marijuana regulated under this rule that may be analyzed for testing or for research and development purposes.
27. **Sampler** means a person authorized to collect samples of marijuana and marijuana products.
28. **Sampling date** means the date that a sample was collected from the manufacturer, in order to be reported as such, when reporting the sample results to marijuana testing facility clients.
29. **Tetrahydrocannabinol (THC and delta-9 THC)** is substance defined in Chemical Abstracts Service number 1972-08-3.
30. **Track and trace system** means the record-keeping required and approved by the Department for registered caregivers, dispensaries, and manufacturing facilities to monitor inventory and transfers of marijuana for medical use for compliance purposes.
31. **Visitor** means any person, other than officer, assistant, or employee of the manufacturing facility, who enters into any areas of the manufacturing facility where marijuana is manufactured or stored.

Section 2 – Authorized Manufacturing; Patient, Caregiver and Dispensary Conduct

2.1 – Authorized Marijuana Manufacturing

2.1.1. Limited Authorization. A person or entity may not manufacture marijuana products or marijuana concentrate for medical use, including all forms and derivatives of the cannabis plant cultivated under 22 MRS, chapter 558-C, in whole or in part, except as explicitly authorized by and in accordance with this rule.

- A. A qualifying patient, caregiver or registered dispensary may manufacture marijuana to produce marijuana product and marijuana concentrate for medical use as authorized in accordance with this rule, including limits on possessing and transferring marijuana and marijuana products for medical use.
- B. A person or entity who is not a qualifying patient, caregiver or dispensary is required to apply for manufacturing facility registration to be authorized to manufacture marijuana for medical use. The person or entity not otherwise authorized to possess and manufacture marijuana for medical use may apply for a tier 1 or tier 2 manufacturing facility registration.
- C. A caregiver or dispensary must apply for a manufacturing facility registration to manufacture marijuana for medical use on behalf of another caregiver or dispensary or to manufacture marijuana that is donated or acquired by wholesale.
- D. An inherently hazardous substances registration (IHS registration) is required for any person or entity using inherently hazardous substances to extract marijuana, including a qualifying patient, exempt caregiver, or a freestanding person or entity. A tier 1 or 2 manufacturing facility is only authorized to extract with inherently hazardous substances if it also has an IHS registration.
- E. Any natural person, including but not limited to officers or directors and assistants or employees, involved in manufacturing under these rules is required to hold a registry identification card as specified under 22 MRS §2425-A(2) and 22 MRS §2423-F(8)(B).

2.1.2. Permissible and Impermissible Activities. A person or entity manufacturing marijuana for medical use, whether or not required to register, must comply with all relevant Department rules.

- A. No qualifying patient, caregiver, dispensary manufacturing facility or IHS registrant may employ or be a person who is under 21 years of age.
- B. Manufacturing must be performed in a manner that results in the amount of marijuana and cannabinoid content within the portion or part of the product containing marijuana or marijuana concentrate being homogeneous throughout the product and consistent with product labeling.
- C. Manufacturing edible products containing marijuana for medical use requires compliance with 22 MRS §2429-C, except that patients who manufacture edible products only for themselves, and exempt caregivers who manufacture edible products for their family members, or members of their household, in accordance with Department rules, are exempt.
- D. A registered caregiver, dispensary, tier 1 manufacturing facility or tier 2 manufacturing facility producing an edible marijuana product must obtain a food establishment license.
- E. Manufacturing-related equipment may not be used to simultaneously manufacture medical use marijuana with marijuana cultivated under the *Marijuana Legalization Act*, 28-B MRS, chapter 1.
- F. A person or entity manufacturing marijuana under this rule must utilize reliable instruments and devices suitable for the weighing of the amount and kind of material to be weighed to uniformly and consistently calculate and report the amount of all forms of marijuana for medical use on the premises. The Department may require a statement of measurement or amount and investigate variations from the declared weight or counts for compliance purposes.
 - (1) Units of harvested marijuana weight must be declared and expressed in pounds, kilograms, grams or milligrams.
 - (2) Units of liquid measure must be declared and expressed in liters or milliliters.
 - (3) Units must be expressed in terms of the largest whole unit with any remainder being in decimal fractions of the unit.
 - (4) Whole numbers may be used in the statement of count for plants, packages and servings per package.
 - (5) Pursuant to 22 MRS §2430-E(4), the calculation of the weight of marijuana that is not dried may be adjusted by a percentage to reasonably account for moisture content of the marijuana that is in

need of further manufacturing. The date of harvest and conditions are factors to consider for weight.

- (6) A calculation of the weight of marijuana in a marijuana product may not include ingredients in the product other than marijuana, except that the weight of marijuana concentrate must be included whether the marijuana concentrate is possessed by itself or within a marijuana product.
- G. No registered caregiver, dispensary or manufacturing facility may produce any marijuana manufactured product or marijuana concentrate in the distinct shape of a human, animal or fruit, or a shape that bears the likeness or contains the characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
- H. No registered caregiver, dispensary, or manufacturing facility may transfer or offer to transfer a marijuana manufactured product or marijuana concentrate that did not pass a test required by the Department and performed by a licensed marijuana testing facility.
- I. Any marijuana, marijuana product or concentrate that fails a test required by the Department to verify or analyze the potency or the presence of residual solvents or other potential contaminants may not be dispensed unless remediated and the subsequent sample passes required testing.
- J. Only approved inherently hazardous substances may be used by a person or entity registered with the Department. No Class 1 solvents may be used to manufacture marijuana.

2.2 – Qualifying Patient Authorized Manufacturing

- A. A qualifying patient, who is not a visiting patient, may possess up to eight pounds of marijuana for medical use. A visiting qualifying patient may possess no more than two and one-half ounces of marijuana obtained from a registered caregiver or dispensary in a 15-day period.
- B. A qualifying patient, including a visiting patient, may prepare marijuana, marijuana concentrate and marijuana products for medical use using the marijuana cultivated pursuant to 22 MRS, chapter 558-C.
- C. A qualifying patient may manufacture extracts or concentrates using only generally safe extraction methods and potentially hazardous extraction methods using ethanol, including solutions of ethanol and potable water (See Section 4.1). Any other extraction methods are prohibited unless a registration to use inherently hazardous substances is obtained in accordance with this rule.
- D. A qualifying patient, including a visiting patient, may provide marijuana cultivated under Chapter 558-C to an appropriately registered caregiver, dispensary or manufacturing facility for that caregiver, dispensary or facility to manufacture a product or concentrate on behalf of the qualifying patient.
- E. A qualifying patient may not sell marijuana, or be otherwise compensated for furnishing marijuana to another person, or for assisting in the preparation of a marijuana product for, or on behalf of, another person. A qualifying patient, except a visiting patient, may furnish up to two and one-half ounces of marijuana to another qualifying patient if nothing is transferred in return or provided to the qualifying patient as compensation or remuneration.

2.3 – Caregiver Authorized Manufacturing

2.3.1. Exempt Caregiver Authorized Manufacturing.

- A. An exempt caregiver may prepare marijuana, marijuana concentrate and marijuana products for medical use using the marijuana cultivated pursuant to 22 MRS, chapter 558-C for a family member or member of the caregiver's household.. The caregiver may manufacture extracts or concentrates using only generally safe extraction methods and potentially hazardous extraction methods using ethanol, including solutions of ethanol and potable water (see Section 4.1). Any other extraction methods or solvents are prohibited unless a registration to use inherently hazardous extraction methods is obtained in accordance with this rule.
 - (1) An exempt caregiver may not possess any more than eight pounds of harvested marijuana for medical use, including marijuana contained in marijuana manufactured products and concentrated marijuana concentrate.
 - (2) An exempt caregiver is prohibited from assisting more than two qualifying patients.

- (3) An exempt caregiver using inherently hazardous substances must obtain an inherently hazardous substance registration from the Department.
 - (4) An exempt caregiver may accept a limited amount of marijuana for medical use, as authorized under Chapter 558-C, to assist a qualifying patient who is a member of the caregiver's family or household.
 - (5) Any caregiver who manufactures marijuana or marijuana concentrate on behalf of another caregiver or dispensary must apply for a tier 1 or tier 2 manufacturing facility registration.
- B. An exempt caregiver producing edible products containing marijuana for medical use is not required to obtain a food establishment license in accordance with 22 MRS §2152, if the caregiver is providing the manufactured product only to the qualifying patient who is a family or household member.
- (1) An exempt caregiver is restricted to transferring no more than two and one-half ounces of marijuana to a qualifying patient at one time, except that, if the patient is a visiting qualifying patient, the caregiver is limited to transferring no more than two and one-half ounces to that visiting patient during a 15-day period.
 - (2) An exempt caregiver may provide marijuana cultivated for medical use to registered caregiver, dispensary or tier 1 or tier 2 manufacturing facility to produce, on behalf of the caregiver, a marijuana product or concentrate for a qualifying patient who is a member of that caregiver's family or household.
 - (3) An exempt caregiver is permitted to be compensated for providing marijuana for medical use to a qualifying patient who is a member of the caregiver's family or household. A caregiver exempt from registration may not be compensated for cultivating or furnishing marijuana plants, product or concentrate to anyone other than a family or household member.

2.3.2. Registered Caregiver Authorized Manufacturing. A registered caregiver must electronically enroll in the track and trace system chosen by the Department and pay required costs. Costs to use the monitoring system may include the vendor's monthly license fee(s) and individual charges for identification tags that may be required to properly identify marijuana plants and marijuana products or concentrates. The registered caregiver must also comply with data collection and reporting requirements of the track and trace system implemented by the Department for all inventory and transfers.

- A. A registered caregiver is permitted to possess and manufacture the total amount of marijuana produced by the registered caregiver's cultivation under Chapter 558-C. A registered caregiver may manufacture marijuana the caregiver cultivated under Chapter 558-C to produce marijuana products and marijuana concentrate for medical use. The registered caregiver may manufacture extracts or concentrates using only generally safe extraction methods and potentially hazardous extraction methods using ethanol, including solutions of ethanol and potable water (see Section 4.1). Any other extraction methods or solvents are prohibited unless a registration to use inherently hazardous substances is obtained in accordance with this rule.
- B. A registered caregiver may provide marijuana for medical use to an appropriately registered caregiver, dispensary or tier 1 or tier 2 manufacturing facility to produce, on behalf of the registered caregiver, a marijuana product or concentrate for a qualifying patient.
 - (1) A registered caregiver who provides a qualifying patient prepared marijuana or marijuana product or concentrate manufactured using only the medical use marijuana cultivated by the caregiver and not using inherently hazardous substances is not required to register as a manufacturing facility.
 - (2) A registered caregiver using inherently hazardous substances to extract marijuana must obtain an inherently hazardous substance registration from the Department.
 - (3) A registered caregiver who manufactures marijuana and marijuana concentrate on behalf of another caregiver or dispensary is required to apply for a tier 1 or tier 2 manufacturing facility registration.
- C. A registered caregiver is responsible for ensuring all marijuana plants, manufactured marijuana and marijuana concentrate are packaged and labeled in accordance with 22 MRS §§2429-A and 2430-G.

- D. As part of a wholesale transaction, a registered caregiver may, in accordance with 22 MRS §2423-A (2)(K-1), acquire marijuana as inventory from another registered caregiver or dispensary. All marijuana plants, manufactured marijuana and marijuana concentrate must be stored securely, labeled for content, and accounted for in the track and trace system required by the Department.
- (1) The registered caregiver is required to obtain a tier 1 or tier 2 manufacturing facility registration if the registered caregiver manufactures wholesale marijuana or further processes wholesale or donated marijuana on behalf of another caregiver or dispensary.
 - (2) The registered caregiver is not required to obtain a tier 1 or tier 2 manufacturing facility registration if the caregiver acquires, in wholesale, or by donation, marijuana, marijuana product or concentrate from a source authorized under Chapter 558-C and no further manufacturing is done by the registered caregiver to provide that marijuana to a qualifying patient for medical use.
- E. A registered caregiver producing edible products containing the marijuana for medical use is required to obtain a food establishment license in accordance with 22 MRS §2152 and comply with any required testing and all applicable food safety standards.
- F. A registered caregiver may conduct testing on manufactured marijuana for research and development purposes. Only the analysis conducted by a licensed marijuana testing facility may be reported for testing required by the Department.

2.4 – Dispensary Authorized Manufacturing

To assist qualifying patients with medical use of marijuana, a registered dispensary is permitted to possess and manufacture all marijuana produced from the plants cultivated by the dispensary under 22 MRS, chapter 558-C for a qualifying patient's medical use.

- A. A registered dispensary that manufactures marijuana for medical use must comply with tracking and record requirements established by 22 MRS §2430-G; and must establish credentials for and utilize any track and trace system implemented by the Department whenever such a system takes effect.
- B. A dispensary manufacturing only the medical use marijuana cultivated by that dispensary and not using inherently hazardous substances is not required to register as manufacturing facility.
- C. A dispensary is required to register as a tier 1 or tier 2 manufacturing facility if the dispensary manufactures on behalf of a caregiver, another dispensary, or manufacturing facility using marijuana provided to the dispensary by donation or wholesale transaction.
- D. The dispensary is not required to obtain a manufacturing facility registration if the dispensary acquires marijuana for medical use from a source authorized under 22 MRS, chapter 558-C and no further manufacturing by the dispensary is needed for the dispensary to provide that marijuana to a qualifying patient.
- E. A dispensary using inherently hazardous substances in marijuana extraction must obtain an inherently hazardous substance registration from the Department.
- F. A dispensary that does not have an inherently hazardous substances registration may manufacture extracts or concentrates using only generally safe extraction methods and potentially hazardous extraction methods using ethanol, including solutions of ethanol and potable water.
- G. The dispensary is permitted to dispense up to two and one-half ounces of harvested marijuana to a qualifying patient in one transaction, except that a dispensary assisting a visiting qualifying patient may not dispense more than two and one-half ounces of harvested marijuana to the visiting qualifying patient during a 15-day period. All transactions must be documented.
- H. The registered dispensary is responsible for ensuring all marijuana plants, manufactured marijuana and marijuana concentrate are labeled and packaged in accordance with 22 MRS §§2429-A and 2430-G.
- I. If the dispensary is manufacturing edible products containing marijuana, the dispensary is required to obtain a food establishment license in accordance with 22 MRS §2152 and comply with any required testing and all applicable food safety standards.

- J. A dispensary may conduct testing on manufactured marijuana for research and development purposes. Only the analysis conducted by a licensed marijuana testing facility may be reported for testing required by the Department.

Section 3 – Authorized Manufacturing Conduct for Tier 1 and Tier 2 Manufacturing Facilities and IHS Registrants

The marijuana facility applicant must fulfill the following general requirements to apply for and annually renew a registration with the Department for manufacturing marijuana for medical use. Unless otherwise specified, all requirements of this section apply to tier 1 and tier 2 marijuana manufacturing facilities; patients, caregivers, dispensaries, and free-standing entities using inherently hazardous substances; and caregivers and dispensaries that manufacture marijuana or marijuana products on behalf of other authorized entities. Only facilities located and operating within the State of Maine may apply for registration. A marijuana manufacturing registration issued by the Department does not authorize the facility to cultivate marijuana or engage in retail sales of marijuana, nor does it exempt the facility from electrical permitting and inspection or food establishment licensing requirements.

3.1– General Provisions

3.1.1. General Requirements for Manufacturing Facility and Inherently Hazardous Substance Use Registration

- A. Applications for registration must be in the name of the proprietors, partners, or corporation that directly owns the business. Applicants must be truthful on all application forms, attachments, and additional information required by the Department.
- B. A marijuana manufacturing registration or inherently hazardous substances registration may not be issued unless the applicant has:
 - (1) Provided a valid form of identification, verifying the applicant(s) is age 21 or older;
 - (2) Completed all application forms prescribed by the Department;
 - (3) Paid all required fees;
 - (4) Submitted to a criminal history check conducted within the most recent 12 months for the applicant, and all principal owners, board members and assistants;
 - (5) Demonstrated that the applicant has received local authorization to conduct manufacturing activities and/or use inherently hazardous substances if required by 22 MRS, chapter 558-C and these rules; and
 - (6) Provided all additional documentation and information required by the application or Department.
- C. A registration is valid only after the person or entity completes any enrollment process required by the Department, including payment of required fees and costs associated with use of the track and trace system.
- D. A person required to register as a manufacturing facility or obtain an inherently hazardous substances registration must obtain a Department-issued registry identification card. If an entity, all facility directors, principal officers, board members, principal owners, employees and assistants must obtain a registry identification card.

3.1.2. Local Authorization for Manufacturing Facilities and the Use of Inherently Hazardous Substances

All applicants seeking to register a marijuana manufacturing facility and/or use inherently hazardous substances in a municipality pursuant to 22 MRS, chapter 558-C, must provide to the Department proof of local authorization to operate such a facility and/or use inherently hazardous substances. Local authorization must be indicated on forms provided by the Department and must include as an attachment a copy of any local ordinance or warrant article authorizing the applied-for conduct. In order to obtain from the Department a Local Authorization Form, the applicant must provide to the Department, in writing, the following information:

- A. The name and date of birth of the applicant;
- B. The type of manufacturing facility (tier 1 or 2) and/or a list of all inherently hazardous substances and potentially hazardous extraction methods to be used in the manufacture and extraction of marijuana, marijuana concentrate, and marijuana products;
- C. A description of the manufacturing activities that will occur on the premises;

- D. A diagram of the premises illustrating in which areas of the premises each manufacturing activity will occur;
- E. If the property is also used as a residence, the location of that residence within the property and plans for complete separation of that residence from the facility including:
 - (1) An entirely separate entrance from a public right of way; and
 - (2) Acknowledgement that no solvent extraction will occur in the same building or structure where the residence is located;
- F. A diagram illustrating the areas of the premises where any solvent, chemical and other inherently and/or potentially hazardous substances will be stored;
- G. If required, the name, education and relevant experience of the person overseeing food safety procedures and requirements;
- H. Equipment to be used, including UL or other safety listing;
- I. Standard operating procedures for each process to be used to manufacture a marijuana product;
- J. Plans for ventilation and filtration systems that prevent marijuana odors from significantly altering the environmental odor outside, while reducing the risk of fire or respiratory harm within the facility;
- K. Any extraction methods and solvents to be used for extraction;
- L. Background screening process for employees;
- M. Plans for compliance with a relevant food safety, refrigeration, storage and sanitary standards;
- N. Plans for compliance with packaging, labeling and other requirements;
- O. Plans for disposal of marijuana and marijuana product waste;
- P. A list of all safety and personal protective equipment to be used on the premises; and
- Q. Plans for compliance with all applicable building and electrical codes and federal and state environmental requirements.

3.2– Tier 1 and Tier 2 Manufacturing Facilities

3.2.1. Registration Requirements. Any person or entity manufacturing marijuana or marijuana products for medical use must register as a tier 1 or tier 2 manufacturing facility unless that person or entity is a patient, caregiver, or dispensary acting in compliance with 22 MRS, chapter 558-C and all Department rules and engages in conduct explicitly exempted from registration in Sections 2.2, 2.3 or 2.4 of this Rule.

3.2.2. Tier 1 and Tier 2 Manufacturing Facility Authorized Manufacturing.

- A. A registered tier 1 or tier 2 manufacturing facility may possess harvested marijuana for manufacturing marijuana and marijuana products for medical use:
 - (1) Pursuant to 22 MRS §2324-F(1) a tier 1 manufacturing facility may possess up to 40 pounds of harvested marijuana.
 - (2) Pursuant to 22 MRS §2423-F(2) tier 2 manufacturing facility may possess up to 200 pounds of harvested marijuana.
- B. A tier 1 or tier 2 manufacturing facility must track all inventory, including all transactions and transfers, in accordance with Department rules.
- C. The facility is required to monitor possession limits using scales validated by weights and measure standards.
- D. The facility must keep physically separate and account separately for marijuana and marijuana products regulated under this Section and any other marijuana the facility may be authorized to possess, including without limitation marijuana or marijuana products intended for adult use if the facility is also licensed for this purpose.
- E. A registered tier 1 or tier 2 manufacturing facility may only engage in marijuana extraction using inherently hazardous substances if it obtains an IHS registration issued by the Department.
- F. A registered manufacturing facility is required to track and trace inventory, transactions and transfers using the electronic system designated by the Department.
 - (1) A registered manufacturing facility must maintain scales to reliably measure, manage and report inventory.

- (2) Any marijuana waste or abandoned marijuana product must be accounted for in the manufacturer's electronic record.
- G. The registered manufacturing facility must ensure that all proprietors, partners, board members, officers and assistants have valid registry identification cards.
- H. A registered manufacturing facility may manufacture marijuana products or marijuana products using methods that are considered generally safe and potentially hazardous extraction methods using ethanol, including solutions of ethanol and potable water (see Section 4.1). Any other extraction methods or solvents are prohibited unless a registration to use inherently hazardous extraction methods is obtained in accordance with this rule.
- I. Manufacture must be performed in a manner that results in the amount of marijuana or concentrate, and cannabinoid content within the product being homogeneous throughout the product and consistent with product labels.
- J. A registered manufacturing facility may manufacture edible marijuana products or tinctures only if it acquires a food establishment license pursuant to 22 MRS §2167.
- K. A registered manufacturing facility may accept harvested marijuana from a qualifying patient, registered caregiver, dispensary, or another registered marijuana manufacturing facility to manufacture a marijuana product or concentrate for that person or entity. The facility must transfer to that person or entity, in return, all the marijuana products and marijuana concentrate produced using the marijuana provided to the facility. The facility may not cultivate marijuana, engage in retail sale or participate in any way to transfer marijuana except as provided in 22 MRS §2423-F(4).
- L. A registered manufacturing facility may conduct testing of marijuana products or marijuana concentrate manufactured by the facility for research and development purposes. Only testing performed by a licensed marijuana testing facility will be accepted when the test is required by the Department.
- M. A registered manufacturing facility may receive reasonable compensation for producing marijuana products and marijuana concentrate.

3.3 – Manufacturing Facility Application Requirements

An application for initial registration or annual renewal for a tier 1 or tier 2 manufacturing facility must be filed with the Department. Any incomplete applications will not be processed and may be returned. A complete application for registration includes the completed application form prescribed by the Department along with all information required in the application forms approved by the Department.

- A. Without limitation, required information includes:
 - (1) A valid email address that the Department may use to send notice to the facility;
 - (2) The physical address of the premises where an applicant will engage in the activities authorized under this section;
 - (3) The name, address and date of birth of each proprietor, principal officer, director, board member and assistant of the facility or entity;
 - (4) A notice indicating whether the applicant plans to engage in extraction involving inherently hazardous substances and whether it meets the requirements of Section 4.1 of these rules;
 - (5) A premises diagram of the manufacturing facility that includes a brief statement of the principal activity to be conducted in each room or partitioned area, including where inherently hazardous substances may be used;
 - (6) The name of each facility director or principal officer in charge of the manufacturing facility and each facility director or principal officers' qualifications or job descriptions;
 - (7) Resumes that document appropriate experience and education for personnel specified in Section 7;
 - (8) The type of manufacturing registration for which the applicant is applying;
 - (9) A copy of standard operating procedures specified on the application forms;
 - (10) Payment of the non-refundable application fee; and
 - (11) If required by these rules, proof that the entity seeking registration has received local authorization from the municipality where manufacturing and/or extraction activities will be conducted.

- B. The facility is responsible for complying with the program-related information sent electronically to the email on record.
- C. When the facility or entity changes its physical location, and when a person registered under this subsection changes the location at which the person engages in activities authorized under this section, the facility, entity or person must notify the Department prior to the relocation

3.4 – Inherently Hazardous Substance Registrants

3.4.1. Registration Requirements. Any person or entity manufacturing marijuana concentrate using inherently hazardous substances or potentially hazardous substances other than ethanol must obtain an IHS registration certificate from the Department. Any person or entity that has notified the Department of its intent to engage in extraction using inherently hazardous substances in accordance with 22 MRS §2423-F(3)(A)(4) and is otherwise in compliance with 22 MRS §2423-F(3)(A) may continue to operate pending issuance of an IHS registration from the Department.

3.4.2. Authorized Manufacture Using Inherently Hazardous Substances

- A. IHS registrants may possess harvested marijuana for IHS extraction for medical use:
 - (1) A freestanding IHS registrant who applies and is registered may possess up to 40 pounds of harvested marijuana.
 - (2) A registrant that is also a qualifying patient, exempt caregiver, registered caregiver or tier 1 or tier 2 registered manufacturing facility may possess up to 40 pounds of harvested marijuana in addition to any other marijuana the registrant is authorized to possess.
- B. A registered manufacturing facility is required to track and trace inventory, transactions and transfers using the electronic system chosen by the Department.
 - (1) A marijuana facility registrant must electronically enroll in the track and trace system by the Department and pay required costs. Costs to use the monitoring system may include the vendor's monthly license fee(s) and individual charges for identification tags that may be required to properly identify marijuana plants and marijuana products or concentrates.
 - (2) A registered manufacturing facility must maintain scales to reliably measure, manage and report inventory.
 - (3) Any marijuana waste or abandoned marijuana product must be accounted for the manufacturer's electronic record.
 - (4) The facility is required to monitor possession limits using scales validated by weights and measure standards.
- C. The facility must keep physically separate and account separately for marijuana and marijuana products regulated under this section and any other marijuana the facility may be authorized to possess, including without limitation, marijuana and marijuana products intended for adult use if the facility is also licensed for that purpose.
- D. The IHS registrant may manufacture marijuana concentrate using inherently hazardous substances for extracting marijuana as provided in this rule.
- E. The IHS registrant must ensure that all assistants have a valid registry identification card.
- F. The IHS registrant may accept harvested marijuana from a qualifying patient, a registered caregiver or a registered caregiver, or dispensary, to manufacture marijuana concentrate for that person or entity. The facility must transfer to that person or entity, in return, all marijuana concentrate produced using the marijuana provided to the facility. The facility may not cultivate marijuana, engage in retail sale or participate in any way to transfer marijuana except as separately authorized in 22 MRS, chapter 558-C.

- G. The IHS registrant may conduct testing of marijuana concentrate manufactured by the facility for research and development purposes. Only testing performed by a licensed marijuana testing facility will be accepted when the test is required by the Department.
- H. The IHS registrant may receive reasonable compensation for producing marijuana concentrate.
- I. The IHS registrant is prohibited from modifying equipment after a professional engineer certifies the equipment as approved in writing by the engineer.
- J. Use of unauthorized solvents by the registrant may result in an immediate revocation of registration.

3.5 – Inherently Hazardous Substance Registration—Additional Application Requirements

Any qualifying patient, caregiver, dispensary, or other manufacturing facility intending to use inherently hazardous substances in manufacturing must first obtain an inherently hazardous substance registration from the Department. A complete application for registration includes the completed application form prescribed by the Department along with all information required in the application form. Without limitation, required information includes:

- A. Notice to the Department regarding their intent to extract using inherently hazardous substances as required pursuant to 22 MRS §2423-F(3)(A);
- B. A list of any inherently hazardous substances to be used;
- C. The process to be used;
- D. A premises diagram of the manufacturing facility that includes a brief statement of the principal activity to be conducted in each room or partitioned area, including where inherently hazardous substances may be used;
- E. Indication of whether the manufacturing facility is located in the same building as a residence or an area open to the public, along with a description of safety measures to protect the health and safety of other occupants of the building;
- F. Certification by a professional engineer licensed in the State of Maine pursuant to 32 MRS, chapter 19 of the safety and location of the professional grade closed loop equipment used for marijuana extraction and the professional engineer's approval of the standard operating procedures for the marijuana extraction;
- G. Certification by a professional engineer licensed in the State of Maine pursuant to 32 MRS, chapter 19, or a State or authorized local official, that the equipment used for marijuana extraction and the location of the equipment comply with state law and all applicable local and state building codes, electrical codes and fire codes, including the chapters of the most recent National Fire Protection Association Fire Code relating to marijuana extraction facilities; and
- H. Documentation from the manufacturer of the marijuana extraction system, or certification by a professional engineer licensed in the State of Maine, showing that a professional grade, closed-loop extraction system that is capable of recovering the solvents used to produce marijuana concentrate is used by the person or entity.

3.6 – Department Action on Registration Application

In reviewing an application for registration, the Department may take one or more of the following actions:

- A. Reject, deny or refuse to accept an application that is missing information or attachments required by the application;
- B. Investigate applicants to verify all State and local requirements have been satisfied;
- C. Verify all information and attachments to the application;
- D. Investigate any and all applicants, assistants, and board members named in the application to ensure no person or individual has a disqualifying drug offense;
- E. Request additional information in order to fully verify all requirements for registration;

- F. Permit the applicant to voluntarily withdraw the application; or
- G. Extend the period of time for applicants to correct or cure applications that fail to meet requirements for registration by the Department.

3.7 – Denial of Application

3.7.1. Grounds for Denial of Application. The following acts or conditions may provide grounds for the Department to deny a registration application:

- A. The applicant(s) or any principal officer, board member or assistant of the applicant:
 - (1) Makes false statements or material omissions in connection with the application or during the verification of information in the application or its attachments;
 - (2) Fails to cooperate with Department during the application process, which may include an inspection of the premises used for manufacturing activities;
 - (3) Fails to submit information requested as part of a complete application; or
 - (4) Fails to meet any of the requirements for registration;
- B. The applicant(s) or any principal officer, board member or assistant of the applicant or person or entity authorized to engage in marijuana extraction has a disqualifying drug offense, or would be denied an approval, credential, certification, authorization or renewal under Title 20-A, section 6103 or 13011 based on that criminal history record check;
- C. The applicant makes any changes affecting the accuracy and completeness of the application, including without limitation:
 - (1) Changes to ownership, board members and required personnel;
 - (2) Changes of location; or
 - (3) Changes to corporate structure; or
- D. The applicant engaged in marijuana extraction using inherently hazardous substances without first notifying and registering with the Department to conduct such activities. Except that any person or entity that has notified the Department of its intent to engage in extraction using inherently hazardous substances in accordance with 22 MRS §2324-F(3)(A) may continue to operate pending issuance of an IHS registration from the Department and such operation prior to registration shall not be considered grounds for denial of the registration application.

3.7.2 Process for Denial; Appeal. The Department will establish an objective process pursuant to the *Maine Administrative Procedure Act*, 5 MRS, chapter 375.

- A. If the Department denies an application for a registration, it will notify the applicant in writing and provide reason for denial.
- B. A denial of an application for registration is a final agency action, subject to judicial review. The Department may provide the opportunity for an administrative hearing.

3.8 – Annual Renewal of Registration

- A. Registration is valid for up to one year from the date of issuance. A registrant for a marijuana manufacturing facility must apply for renewal of the registration no later than 60 days prior to the expiration of the current registration term to avoid lapse of authorization.
- B. The Department may accept a renewal application within 60 days of the current registration's expiration date.
- C. The Department may administratively extend the expiration date of a registration, provided the registrant has submitted a complete renewal application.

- D. A registrant may not operate or exercise the privileges of the registration at any time if the registration is expired, unless expressly agreed to in writing by the Department.

3.9 – Annual Criminal History Record Check

- A. A marijuana manufacturing facility registrant or an applicant, and any principal officer, board member or assistant of a manufacturing facility is subject to annual criminal history checks beyond initial registration.
- B. A registrant or an applicant and any principal officer, board member or assistant of a manufacturing facility must disclose all convictions of a disqualifying drug offense for the 10 years prior to the date of the application.
- C. A registrant or an applicant, and any principal officer, board member or assistant of a manufacturing facility must provide court dispositions and other information requested by the Department for each conviction that is a disqualifying drug offense.
- D. Any person subject to a criminal history record check who is administering marijuana on school grounds may be required to submit to fingerprinting and pay any associated fee. Fingerprints may be forwarded to the State Bureau of Identification (SBI) for State and national criminal history record checks. The person or entity who has an expired or revoked registration and is not subject to this rule may submit a written request to remove a fingerprint from the SBI files.

3.10 – Application Fees

An applicant is required to pay the following fees for initial manufacturing facility and/or IHS registration and annual renewal:

- A. Tier 1. The annual fee for registering and renewing a tier 1 manufacturing facility registration is \$150.
- B. Tier 2. The annual fee for registering and renewing a tier 2 manufacturing facility registration is \$250.
- C. IHS registration. To use inherently hazardous substances for marijuana extractions, a qualifying patient, caregiver, dispensary, tier 1 manufacturing facility, or tier 2 manufacturing facility is required to complete an IHS registration application, including payment of the IHS registration fee of \$350.
- D. The cost of a criminal history check required for the applicant is \$31 for each background check conducted through the State Bureau of Identification, and \$60 if a federal or national background check is conducted.
- E. All application fees are non-refundable.

Section 4 – Inherently Hazardous Substances

Extraction of medical marijuana shall be permitted as stated below and in accordance with this rule. All other extraction methods and substances are forbidden.

4.1 – Extraction Methods

Extraction of medical marijuana shall be permitted as stated below and in accordance with this rule. All other extraction methods and substances are forbidden.

4.1.1 Generally safe extraction methods. The Department permits, without an inherently hazardous substance registration, the following generally safe extraction methods, so long as they are done by a person or entity authorized pursuant to this rule:

- A. Mechanical extraction using:
 - (1) Potable water and ice made from potable water;
 - (2) Dry screening or sieving;
 - (3) Cryogenic or subzero manufacturing not involving a solvent; or
 - (4) Pressure and temperature.
- B. Infusion of marijuana in food grade fats or synthetic food additives:
 - (1) Propylene glycol;
 - (2) Glycerin,
 - (3) Butter;
 - (4) Olive Oil;
 - (5) Other typical cooking fats.

4.1.2 Potentially hazardous extraction methods.

The Department will permit, without an inherently hazardous substance registration, potentially hazardous solvent extraction using a 99 percent or greater purity of the following solvents, using appropriate storage, preparation, electrical, gas monitoring, fire suppression and exhaust systems methods and with an end result that does not exceed allowable limits specified by the Department:

- (1) Ethanol, including solutions of ethanol and potable water.

4.1.3 Inherently hazardous extraction methods. The Department will permit a manufacturing facility with an inherently hazardous substance registration to perform inherently hazardous solvent extraction using a 99 percent or greater purity of the following solvents, so long as the solvents are listed in the inherently hazardous substance registration and the end result does not exceed allowable limits specified by the Department:

- A. Butane;
- B. Propane;
- C. Acetone;
- D. Heptane;
- E. Pentane; or
- F. Any other liquid chemical, compressed gas, commercial product with a flash point at or below 100 degrees Fahrenheit, or CO₂, so as the solvent is approved by the Department in writing.

4.1.4. Additional Precautions for Extraction using Potentially Hazardous or Inherently Hazardous Substances.

- A. All flammable gas must be odorized in compliance with state and federal regulations.
- B. Pressurized canned flammable fuel, including without limitation butane or propane in containers intended for camp stoves, handheld torch devices, refillable cigarette lighters and similar consumer products, are prohibited for use in extraction.
- C. A manufacturing facility performing potentially hazardous or inherently hazardous extraction shall be subject to inspection by the local fire department, building inspector and/or code enforcement officer to confirm that no health or safety concerns are present.
- D. Any person or entity registered to use inherently hazardous substances must comply with requirements of the registration including but not limited to utilizing closed loop systems, meeting minimum required security measures, and obtaining necessary documentation, in accordance with 22 MRS 2423-F (3).
- E. Any person or entity registered to use inherently hazardous substances may be required to demonstrate capability of recovering the solvents used to produce marijuana for medical use.

4.2 – Extraction by Patients

- A. An inherently hazardous substance registration issued to a qualifying patient does not permit the qualifying patient to have assistants or employees perform extraction.
- B. A qualifying patient registered to use inherently hazardous substances to extract marijuana solely for the qualifying patient's own medical use is not required to enroll in the electronic monitoring system deployed by the Department.

Section 5 – Registered Manufacturing Facility Policies and Procedures

5.1 – Standard Operating Procedures

- A. Each registered manufacturing facility must maintain written standard operating procedures that are easily accessible to on-site personnel for each product or concentrate it manufactures.
- (1) Standard operating procedures must be available for review on-site when requested by the Department.
 - (2) Those procedures that the facility considers a trade secret must be clearly identified by the facility. The Department may consider specified trade secrets confidential if it determines such procedures meet the definition of trade secrets in 10 MRS §1542(4), except procedures or practices that are determined hazardous to public health and safety and violate authorizations of the Act are not trade secrets.
- B. The standard operating procedures must, at minimum, include the following:
- (1) Detailed step-by-step instructions of each required process to manufacture marijuana products or concentrate, including but not limited to methods, use of equipment in accordance with manufacturer's instructions, and applicable sanitary rules and safety measures.
 - (2) For extraction involving inherently hazardous substances, additional detailed instructions to:
 - (a) Conduct all necessary safety checks prior to commencing production;
 - (b) Prepare marijuana for manufacturing;
 - (c) Extract cannabinoids and other essential components of marijuana;
 - (d) Purge any solvent or other unwanted components from a marijuana concentrate; and
 - (e) Clean all equipment, counters and surfaces thoroughly;
 - (3) Policies or procedures developed in accordance with the security requirements in Section 6 of these rules;
 - (4) Emergency response procedures, including in case of a fire, chemical spill or other emergency;
 - (5) Inventory control procedures for preventing unlawful diversion of marijuana and for tracking the amount of marijuana in possession of the facility;
 - (6) Waste management procedures in compliance with Section 13 of these rules;
 - (7) Policies and procedures for taking marijuana samples for required testing specified in Section 10 of these rules; and
 - (8) Procedures for organizing tracking batches of marijuana product and concentrates, which includes tracking and reporting weight and/or count.

5.2 – Record Keeping and Audits

5.2.1 Record Keeping.

- A. A manufacturing facility must maintain records of all transfers, inventory, transactions and chain of custody forms for a minimum of one year. All records must be made available to the Department upon request.
- B. The Department, at its sole discretion, may require a registered manufacturing facility to account for all inventory through a centralized track and trace software system. A manufacturing facility must comply with all reporting requirements of the designated electronic data system.
- C. All personnel records must be current and complete.

5.2.2. Internal Audit.

The registered manufacturing facility must conduct an internal audit at least once per year.

- A. The internal audit must at a minimum:

- (1) Examine the manufacturing facility's compliance with the requirements of this rule and identify required updates to, including but not limited to, standard operating procedures, employee records, and training records that must be updated;
 - (2) Report and reconcile any discrepancies in surplus or unaccounted marijuana held in inventory; and
 - (3) Immediately report any material deficiencies and non-compliant findings to the Department along with a plan for correcting deficiencies ("corrective action plan") and gaining compliance.
- B. The Department may take administrative or disciplinary action based on the findings of the audit or place additional reporting requirements as part of a corrective action plan to ensure compliance is obtained.
- C. If no material deficiencies or non-compliant findings are discovered, then the registered manufacturing facility will report the findings of the audit to the Department at the time of application or request.

Section 6 – Manufacturing Facility Security Requirements

6.1 – Security

- A. The manufacturing facility must develop and implement security protocols that can ensure the security and tracking of marijuana on the premises, and prevent diversion, theft and loss of medical use marijuana.
- B. The security protocol must be documented in writing and available to all registered manufacturing facility personnel during normal business hours.
- C. The manufacturing facility must ensure that personnel have a thorough understanding of the security protocol and must take disciplinary action against any owner, officer, assistant or board member who negligently or willfully violates the security protocol.

6.2 – Access Control

The manufacturing facility must deter the unauthorized entrance into its premises by controlling access to those areas through the following means:

- A. Limiting access to specific personnel who have cause to access the area to execute their specific job function and duties;
- B. Implementing an access-control-card system capable of preventing unauthorized access through access control points and recording the transaction history of all entrants;
- C. Using an actively monitored security alarm system;
- D. Installing security cameras at all access points to the premises and in storage areas for medical use marijuana, products and concentrates; and
- E. Maintaining a visitor arrival and departure log, which must contain, at a minimum, the name of the visitor, date and time of arrival and departure, and the purpose of the visit.

6.3 – Storage Areas

- A. The manufacturing facility must store and secure marijuana with a commercial-grade lock in a room or cabinet capable of preventing diversion, theft and loss. Secured areas must be locked at all times, except when managing or retrieving a secured item or items. The total weight, measure or count of marijuana products and concentrates on the premises must be reported for compliance monitoring and auditing purposes.
- B. The registered manufacturing facility must designate secure areas for storage of the following:
 - (1) Marijuana, marijuana products and marijuana concentrates;
 - (2) Test samples of marijuana for medical use;
 - (3) Waste containing marijuana; and
 - (4) Records of analytical tests, including certificates of analyses and data packages.

6.4 – Notification of Discrepancy

Unless otherwise specified, the registered manufacturing facility must notify the Department within one business day of discovering any of the following:

- A. An unexplained loss of 5% or more of the inventory of marijuana, marijuana products or marijuana concentrates held at the registered manufacturing facility;

- B. Diversion or theft of marijuana, any intentional or otherwise severe violations of internal security protocols by assistants, unauthorized or prohibited conduct, or any other criminal activity pertaining to the operation of the manufacturing facility; or
- C. Any individual registrant, principal officer, board member or assistant that has been convicted of a disqualifying drug offense.

Section 7 – Manufacturing Facility Organization

7.1 – Responsibilities of Management

- A. A manufacturing facility must designate a manufacturing facility director who is responsible for ensuring the facility operates in compliance with this rule. If the manufacturing facility is owned by a qualifying patient or caregiver, the owner must be designated as the facility director.
- B. A registered manufacturing facility with more than 5 assistants must identify a principal officer in addition to the facility director.
- C. The management shall ensure that a person-in-charge, who can cooperate with any inspection, on-site assessment or complaint response, is present on the premises of any manufacturing facility during hours of operation or apparent activity.
- D. A registrant, manufacturing facility director, principal officers and person-in-charge are responsible for the management of the manufacturing facility and supervision of its assistants.
- E. Registry identification cards are required for all proprietors, partners, board members, facility directors, principal officers and assistants pursuant to 22 MRS, chapter 558-C. A registry identification card may not be issued to any person who has not attained 21 years of age.
- F. A registered manufacturing facility must:
 - (1) Define the responsibilities of key personnel in the organization who have a management role; and
 - (2) Have policies and procedures to ensure the protection of its qualifying patients' confidential information, including procedures for protecting the electronic storage of confidential information.
- G. A manufacturing facility with an inherently hazardous substances registration must define the responsibilities of key personnel in the organization who will be engaged in extraction using inherently hazardous substances.

7.2 – Director and Principal Officer Qualification Requirements

- A. The facility director and, where applicable, principal officer(s) or person(s)-in-charge must have a high school qualifying degree, diploma or GED Equivalent.
- B. The facility director and, where applicable, principal officer(s) or person(s)-in-charge may not have any conviction of a disqualifying drug offense.

7.3 – Personnel Documentation and Registrations

A manufacturing facility must maintain the following records and present to the Department upon request:

- A. Records of valid registry identification cards for each owner, partner, principal officer, board member and assistant, including the name of the cardholder, the date of issuance and expiration date of the identification card;
- B. A copy of the criminal history record check, if a copy had been provided to the facility by the Department, and unique identification number for each of its owners, partners, principal officers, board members and assistants;
- C. Record of the qualifications of facility director and principal officer(s), or person(s)-in-charge, where applicable; and
- D. Documentation of the responsibilities, training and supervision requirements of Sections 7.1 and 7.4 .

Section 7.4 – Personnel Training and Supervision

The registered manufacturing facility director or principal officer must:

- A. Provide adequate supervision of staff, including trainees, by persons familiar with standard operating procedures;
- B. Ensure all staff has demonstrated capability in the activities for which they are responsible;
- C. Formulate goals for education and training of the facility's personnel;
- D. Have policies and procedures for identifying training needs and providing training of personnel; and
- E. Ensure that the training of the registered manufacturing facility personnel is kept up to date (on-going) by providing the following:
 - (1) Training documentation on equipment, techniques, standard operating procedures and security protocols; and
 - (2) Training in ethical and legal responsibilities.

Section 8 – Packaging, Labeling and Marketing Manufactured Marijuana

Packaging and labeling for all transfers, including wholesale, must specify content and declare the quantity of contents in terms of weight, measure or count; list the registry identification card number and registry identification number of the source, if applicable; date of transfer; the identifier(s) required for the Department’s monitoring system, if any; and results of any required testing conducted by a licensed marijuana testing facility, if any.

Marijuana for medical use on the premises, whether in process, stored or displayed, must be secure, measured and distinguishable from other products. Packaging and labeling must be in accordance with 22 MRS §§2423-F and 2430-G.

8.1 – Packaging Requirements

A registered caregiver, dispensary or manufacturing facility must package all marijuana products and marijuana concentrates prior to transfer to a qualifying patient. The packaging must:

- A. Be tamper-evident and maintain an unbroken seal;
- B. Completely enclose the entirety of marijuana product or concentrate;
- C. Contain labeling on an easily identifiable portion of the packaging as specified in Section 8.2 of this rule; and
- D. Conform to packaging and labeling requirements under applicable licenses held by the manufacturing facility, including required food establishment licenses, if any.

However, nothing in these rules shall be construed to prohibit the packaging of marijuana products or concentrates in reusable packaging provided to the registered caregiver, dispensary, or manufacturing facility by a qualifying patient for the packaging of marijuana products or marijuana concentrates for use by that same qualifying patient, so long as such packaging conforms with the requirements above.

8.2 – Labeling Requirements

- A. All manufactured marijuana products and marijuana concentrates must be labeled and include the following information:
 - (1) The registry identification number of the manufacturing facility;
 - (2) Ingredients other than marijuana contained in the marijuana product or marijuana concentration;
 - (3) Any pesticides, chemicals, solvents or other substances used to manufacture the marijuana product or concentrate;
 - (4) A unique identifier to trace the marijuana used to manufacture the marijuana product or marijuana concentrate. This could be a batch number, track and trace identifier or other means required by the Department.
 - (5) Results from the certificate of analysis for testing required by the Department and performed by a valid licensed marijuana testing facility, if any:
 - (a) If the marijuana product or concentrate has undergone testing by a valid marijuana testing facility, the product or concentrate must bear a label displaying the THC and CBD content of the cannabinoid profile; a yes-or-no indication that the product has passed testing for pesticides, residual solvents and other contaminants; and a link to the online results of the full certificate of analytical results;
 - (b) If the marijuana product or concentrate has not been tested by a licensed marijuana testing facility, and no such test is required, the product or concentrate must display a label with the following disclosure “THIS PRODUCT HAS NOT UNDERGONE TESTING FOR CONTAMINANTS, PESTICIDES, RESIDUAL SOLVENTS OR OTHER CONTAMINANTS BY A LICENSED MARIJUANA TESTING FACILITY.

THIS PRODUCT MAY CONTAIN HARMFUL MATERIAL AND COULD BE HAZARDOUS TO YOUR HEALTH.”;

- (6) A warning indicating that medical marijuana is present, that the marijuana product is not FDA approved, and, the Department’s universal symbol indicating the presence of marijuana; and
 - (7) A warning that marijuana product or concentrate should be kept away from minors and that caution must be exercised before driving or using heavy machinery.
- B. No marijuana product or concentrate label from a registered manufacturing facility may include information about the THC or CBD contents or the profile of the product, or values of any test required by the Department unless the values are based on a homogenized sample tested by an accredited marijuana testing facility, and, if the Department has licensed a marijuana testing facility, values must be reported as provided in the certificate of analysis from a licensed marijuana testing facility, if any.

8.3 – Education Materials

A manufacturing facility must have available for the recipient of the manufactured marijuana educational materials related to the marijuana product or concentrate and any solvents used by the facility. The educational materials must include the following, as applicable:

- A. Identification of the source of each informational material;
- B. Information about methods of administration, the marijuana product or concentrate and how it should be correctly used;
- C. Information on the risks of using marijuana, including prior to driving or operating heavy machinery, during pregnancy or while breastfeeding;
- D. Information about the manufacturing process used to manufacture the marijuana product or concentrate, including any solvents used; and
- E. A recommended dosage guide for edible or tincture products and a warning that effects may take up to two hours to experience. Each 10mg of THC will be considered a dose for purposes of the guide.

Section 9 – Required Testing of Manufactured Marijuana

A person or entity required to register to manufacture marijuana for medical use, including a manufacturing facility or anyone using inherently hazardous substances, may be subject to testing requirements established by the Department. Testing conducted by a marijuana testing facility licensed by the Department is considered valid 3rd party testing to verify product labels and is acceptable for required testing.

Section 10 – Manufactured Marijuana Sampling Requirements

10.1 – Sampling Procedures

- A. A registered manufacturing facility, and IHS registrants must have written standard operating procedures for submitting a sample to a marijuana testing facility which must include:
 - (1) Attaching a label with the date the sample was taken and identified product batch;
 - (2) Obtaining a homogenous sample from a marijuana product and concentrate in its final form prepared for medical use;
 - (3) Procedures for determining the volume of sample to be collected from each production batch;
 - (4) Methods for obtaining a random sample from each production batch of a marijuana product or concentrate in its final form that is representative of the batch;
 - (5) Procedures for maintaining chain of custody forms of the sample;
 - (6) Factors such as storage, environmental conditions and transportation of the batch or sample; and
 - (7) A policy for retaining all documents used in each part of the sampling process and all sampling chain of custody forms. The documents are required for each batch sampled.
- B. A registered manufacturing facility that has samples obtained by a sampler employed by a marijuana testing facility shall comply with that marijuana testing facility's sampling procedures.
- C. A registered manufacturing facility must maintain a copy of all sampling forms used by the marijuana testing facility.
- D. A registered manufacturing facility may not transfer a sample to a testing facility without including a chain of custody form for each sample.
- E. A registered manufacturing facility that has a sample pending and awaiting a certificate of analysis from the marijuana testing facility must quarantine all marijuana product or concentrate from the sampled batch, and refrain from labeling any marijuana products or concentrates produced from the batch until the certificate of analysis has been received from the marijuana testing facility.

10.2 – Certificate of Analysis

- A. A copy of the certificate of analysis that correlates with the marijuana used in the manufacturing must be available to the person or entity receiving the manufactured product or concentrate.
- B. The registered manufacturing facility must retain every certificate of analysis it receives from a marijuana testing facility in accordance with Section 10.1, paragraph E for each sample submitted.

Section 11– Remediation of Manufactured Marijuana

A registered manufacturing facility or IHS registrant may be permitted to remediate a batch of marijuana product or concentrate when the sample tested exceeds the allowable level for residual solvents, or fails potency testing or visual inspection for filth and foreign materials.

- A. If a marijuana product or marijuana concentrate has failed a residual solvent test or a visual inspection for filth and foreign materials, it may be destroyed or remediated in accordance with this rule and the marijuana testing facility's standard, and in a manner that safely and effectively addresses the reason for the failed test result.
- B. If as test is required by the Department, any manufactured marijuana that is remediated after a failed test must be re-sampled and tested again by a licensed marijuana testing facility before the marijuana product or concentrate may be transferred.
- C. When informed of a failed residual solvent test or visual inspection for filth and foreign materials on a marijuana product or marijuana concentrate, the manufacturing facility must remediate or destroy all the failed sample batch and any marijuana products or marijuana concentrate that reasonably would have the same issues.
- D. A registered manufacturing facility may only transfer marijuana products or marijuana concentrates that have failed testing to another manufacturing facility for remediation purposes. The sending manufacturing facility must disclose the failure to the receiving manufacturing facility prior to transfer and provide the test report.
- E. Any registered manufacturing facility engaging in remediation must have standard operating procedures for detecting and removing solvents, filth and foreign materials, and harmful contaminants from a marijuana concentrate or product.
- F. A registered manufacturing facility may not remediate a marijuana product or concentrate when the product or concentrate failed any test for microbials or metals required by the Department.

Section 12– General Reporting Requirements for Manufacturing Facilities

- A. A manufacturing facility must submit the following information to the Department on an annual basis electronically if the Department has implemented a track and trace software system, or if requested by the Department, on forms provided by the Department:
 - (1) A current list of the names of all owners, partners, board members, principal officers, assistants;
 - (2) Annual revenue for the last fiscal year;
 - (3) The number of samples tested by a marijuana testing facility, number of samples that failed testing standards, number of batches destroyed and number of batches remediated;
 - (4) Any standard operating procedures added or modified during the year; and
 - (5) Results of the annual internal audit conducted by the manufacturing facility.
- B. A manufacturing facility registrant must report the following information to the Department within 3 days of discovery:
 - (1) A change in facility director, principal officer or board member; or
 - (2) A conviction of a disqualifying drug offense conviction by an assistant, board member or principal officer.
- C. A manufacturing facility registrant must report to the Department at least 30 days beforehand any change in the physical address of the facility or entity, or the physical address where a registrant who is an individual will engage in the activities authorized under this Rule. The registrant must complete a change of location form.

Section 13 – Waste Disposal Requirements

- A. A registered manufacturing facility must account for and dispose of all marijuana waste in a manner that prevents unlawful diversion and does not violate any other applicable federal, state or local laws and regulations governing the handling of waste.
- B. All marijuana waste must be weighed and recorded from the time it becomes waste until the time it is disposed of in a secured receptacle in the registrant's possession.
- C. Marijuana waste must be rendered unusable and indistinguishable from non-marijuana waste by breaking up, grinding, unpackaging, combining and mixing with other solid waste.
- D. Once marijuana waste is rendered unusable and indistinguishable, it must be placed in a secured receptacle in registrant's possession until it is disposed of in compliance with all federal, state and local laws and regulations.
- E. A registered manufacturing facility may not dispose of marijuana waste in any other way unless such disposal is in conformance with another method approved by the Department or its designee.

Section 14– Enforcement

14.1 – General Provisions

- A. Unless otherwise specified, the Compliance and Enforcement procedures specified in 10-144 CMR, chapter 122, section 10 also apply to manufacturing facilities. Any conduct not authorized under this rule or Chapter 122 is prohibited. If there is a conflict between Chapter 122 and this rule, this rule applies. *(APA Office Note: 10-144 chapter 122 has been relocated to 18-691 chapter 2.)*
- B. Any person or entity required to enroll in the track and trace system or register as a manufacturing facility under this rule has 60 days from the effective date of this rule to enroll and complete an application and obtain local approval. After that time no person or entity may manufacture marijuana or make concentrates using IHS except as permitted in this rule.
- C. Conduct not authorized is prohibited. Violation of these rules or of 22 MRS, chapter 558-C may result in compliance and enforcement actions including directed corrective action; suspension, revocation and denial of a registry identification card or registration certificate; civil penalties; and referral to the appropriate agency, department or entity if the Department determined that the conduct is not appropriate for agency directed corrective action or the violation or deficiency has not been rectified through corrective action.

14.2 – Compliance Inspection

The Department may require an inspection prior to issuance of a manufacturing facility registration. As stated in 22 MRS §2430-G(2)(D), the Department may, without prior notice, inspect premises to ensure compliance with conduct authorized under this rule during regular business hours and hours of apparent activity. The Department will show proof of identity when requesting entry and to inspect an area reportedly used for conduct described under this rule. Prior to entry, the Department will also provide a written statement of the reason for inspection in a standard form.

- A. A registered manufacturing facility or other entity authorized under this rule is required to make available any records, forms, protocols, documents or any other type of information required by the statute and this rule to the Department within ten (10) business days of a request from the Department. Delay may result in progressive enforcement action.
- B. The Department may audit any registered manufacturing facility or other entity authorized under this rule to manufacture medical use marijuana to ensure compliance. The audit may include the tracking system used by the person or entity to record transactions and transfers and the Department's chosen tracking and tracing system.
- C. When the Department is conducting an inspection, the Department will consider refusal to permit entry or access to inspect records or premises or willful avoidance of inspection a failure to comply with provisions of this rule, and upon a second failure to comply with inspections, the Department may take further enforcement action.
 - (1) The Department may refer to law enforcement as a progressive enforcement action when compliance cannot be determined.
 - (2) If denied entry more than one time by a cardholder, the Department may take action to revoke the registry identification card, individual identification card or registration certificate.

14.3 – Court Ordered Fines

- A. The Department may seek a court order imposing fines.
- B. A person who knowingly violates the confidentiality of information protected by 22 MRS, chapter 558-C commits a civil violation for which a fine of up to \$1,000 may be imposed. This provision does not apply to a physician, staff of a hospice provider or nursing facility named as a primary caregiver or any other person directly associated with a physician or a hospice provider or nursing facility that provides services to a registered qualifying patient.
- C. A person who is employed by or is a principal officer or board member of a manufacturing facility, if that person has been convicted of a disqualifying drug offense, commits a civil violation for which a fine of not more than \$1,000 may be adjudged.

14.4 – Department Disciplinary Actions

The Department has the authority pursuant to Title 22, chapter 558-C and Title 5, chapter 375, subchapter 7 to administer disciplinary actions for violations of the statute and this rule.

- A. When taking action, the Department will issue a written notice that includes the following information:
 - (1) The nature of the violation and the specific rule violated;
 - (2) The date the department's action takes effect; and
 - (3) If the Department is taking action to revoke a registration or certificate issued under this rule, the term of revocation for which the person is not eligible to apply for registrations issued by the Department.
- B. A person or entity aggrieved by the Department's actions may pursue the right to appeal the Department's action as provided in the notice by requesting an administrative hearing or informal review.

STATUTORY AUTHORITY:

Title 22 ch. 558-C

EFFECTIVE DATE:

August 1, 2019 – filing 2019-140