

R66. Agriculture and Food, Medical Cannabis and Industrial Hemp.

R66-10. Closed Door Medical Cannabis Pharmacy.

R66-10-1. Authority and Purpose.

- (1) Subsection 4-41a-1206(10) and Subsection 4-2-103(1)(i) authorize this rule.
- (2) This rule establishes operating and licensing requirements and standards to be followed by closed door medical cannabis pharmacies and their employees.

R66-10-2. Definitions.

- (1) "Cannabis waste" means cannabis product that is damaged, deteriorated, mislabeled, expired, returned, subject to a recall, or enclosed within a container or package that has been opened or breached.
- (2) "Card" means a medical cannabis card or registration card, authorized under Title 26B, Chapter 4, Part 2 Cannabinoid Research and Medical Cannabis.
- (3) "Courier agent" means a medical cannabis courier agent.
- (4) "Department" means the Utah Department of Agriculture and Food.
- (5) "DHHS" means The Utah Department of Health and Human Services.
- (6) "Direct supervision" means that a PMP is physically present at a closed door medical cannabis pharmacy facility and immediately available for in-person face-to-face communication with the pharmacy agent.
- (7)(a) "Educational material" means material distributed for an educational purpose by a closed door medical cannabis pharmacy.
- (b) Educational material includes any printed educational material such as a placard, poster, fact sheet, book, pamphlet, flyer, or business card.
- (8) "Pharmacy agent" means a medical cannabis pharmacy agent, as defined in Section 26B-4-201.
- (9) "PIC" means a pharmacist-in-charge who oversees the operation and generally supervises a medical cannabis pharmacy.
- (10) "PMP" means a medical cannabis pharmacy medical provider that meets the criteria defined in Subsection 4-41a-1101(12).
- (11) "Recreational disposition" means:
 - (a) slang words or phrases associated with the recreational use of cannabis;
 - (b) an image of a celebrity or other person whose target audience is children or minors;
 - (c) content that encourages, promotes, or otherwise creates an impression that the recreational use of cannabis is legal or acceptable, or that the recreational use of cannabis has potential health or therapeutic benefits;
 - (d) content that promotes excessive consumption;
 - (e) content that is obscene or indecent; and
 - (f) content that a reasonable person knows or should know appeals to children.
- (12) "Safeguard" means to maintain the confidentiality of the information accessed and not use, release, publish, disclose, or otherwise make available to any other person not authorized

to access the information for any purpose other than those specifically authorized or permitted by applicable law.

(13) "State electronic verification system" means the same as the term is defined in Section 26B-4-202 and Subsection 4-41a-102(44).

(14) "Targeted marketing" means the same as the term is defined in Subsection 4-41a-102(47).

(15) "Total revenue" means the total amount of money that a pharmacy earns through the selling of its medical cannabis products, medical cannabis devices, and services, over a license term.

(16) "Utah resident" means an individual who has established a domicile in Utah.

R66-10-3. Closed Door Medical Cannabis Pharmacy License.

(1) A closed door medical cannabis pharmacy license allows a home delivery medical cannabis pharmacy licensee to store and distribute medical cannabis via delivery from a separate approved location.

(2) Locations for closed door pharmacies shall be approved based on:

- (a) geographic locations defined in Section R66-5-21;
- (b) current pharmacy locations;
- (c) patient needs;
- (d) willingness of a closed door pharmacy to carry all brands;
- (e) policy allowing the PIC to determine pharmacy inventory;
- (f) whether the location is in a county of the first or second class, to ensure compliance with Subsection 4-41a-1206(7)(c);
- (g) operating plan; and
- (h) compliance history.

(3) A complete application shall include:

- (a) a licensing fee, charged pursuant to Subsection 4-41a-1206(1)(d); and
- (b) statements, forms, diagrams, operating plans, and other applicable documents as required by the department in the application.

(4) Before approving an application, the department may contact the applicant and request additional supporting documentation or information.

(5) Before issuing a license, the department shall inspect the proposed premises to determine if the applicant complies with state laws and local ordinances.

R66-10-4. General Operating Standards.

(1) In addition to general operating standards established in Title 4, Chapter 41a, Cannabis Production Establishments and Pharmacies, closed door medical cannabis pharmacies shall comply with the operating standards established in this rule.

(2) Closed door medical cannabis door pharmacies shall:

- (a) be well lit, well ventilated, clean, and sanitary;
- (b) maintain a current list of employees working at the closed door medical cannabis pharmacy that:
 - (i) includes employee name, and work schedule;
 - (ii) is readily retrievable for inspection by the department; and

(iii) is maintained in paper or electronic form;
(c) have current and retrievable editions of the following reference publications, in print or electronic format, readily available and retrievable to closed door medical cannabis pharmacy personnel:

- (i) Title 4, Chapter 41a, Cannabis Production Establishments and Pharmacies;
- (ii) Title 26B, Chapter 4, Part 2, Cannabinoid Research and Medical Cannabis; and
- (iii) applicable administrative rules.

(3) A closed door medical cannabis pharmacy may not prepare medical cannabis products or medical cannabis devices for delivery to a medical cannabis cardholder unless an employee who is a PMP is physically present and immediately available in the closed door medical cannabis pharmacy.

(4)(a) Deliveries to a closed door medical cannabis pharmacy from a cannabis processing facility or a medical cannabis pharmacy shall be received under the direct supervision of a PMP or pharmacy agent.

(b) The PMP or pharmacy agent shall be present to accept the delivery.

(c) Upon delivery, the medical cannabis product or medical cannabis devices shall immediately be placed in a limited access area of the closed door medical cannabis pharmacy.

(5) A closed door medical cannabis pharmacy shall protect confidential cardholder data and information stored in the Electronic Verification System to ensure that access to and use of the data and information is limited to those individuals and purposes authorized under Title 26B, Chapter 4, Part 2, Cannabinoid Research and Medical Cannabis and this rule.

(6) A closed door medical cannabis pharmacy may not dispense expired, damaged, deteriorated, misbranded, adulterated, or opened medical cannabis products or medical cannabis devices.

R66-10-5. Operating Plan.

(1) A closed door medical cannabis pharmacy license application shall include an operating plan to be included in the home delivery pharmacy's operating plan and at a minimum, consists of the following:

(a) the information requested in the application;

(b) a security plan;

(c) storage protocols, both short- and long-term, to ensure that cannabis is stored in a manner that is sanitary and preserves the integrity of the cannabis; and

(d) a plan to comply with applicable operating standards, statutes, and administrative rules, including:

(i) Title 26B, Chapter 4, Part 2, Cannabinoid Research and Medical Cannabis, Title 4, Chapter 41a, Cannabis Production Establishments and Pharmacies; and

(ii) applicable administrative rules; and

(e) procedures for a PIC to determine the closed door pharmacy's medical cannabis inventory under Subsection 4-41a-1101(12).

(2)(a) The department may require the applicant for a closed door medical cannabis pharmacy license to make a change to its operating plan before issuing a license.

(b) The applicant shall submit a copy of its updated operating plan, with the required change and receive department approval of the plan before the department awards the license.

(3) Once the department issues a license, any change to a closed door medical cannabis pharmacy's operating plan is subject to department approval.

R66-10-6. Pharmacist-In-Charge.

(1) PICs shall have the responsibility to oversee the closed door medical cannabis pharmacy's operation.

(2) PICs overseeing a closed door pharmacy shall comply with Sections R66-5-5 and R66-5-6.

R66-10-7. Separation of Closed Door Medical Cannabis Pharmacies and Medical Cannabis Processors in a Single Facility.

(1) Any facility that has both a closed door pharmacy license and a license for medical cannabis processing shall ensure physical separation of medical cannabis intended for home delivery and medical cannabis in the processing facility.

(2) Processing of medical cannabis material may not occur in rooms designated as closed door pharmacy areas.

(3) Medical cannabis intended for home delivery in the closed door pharmacy shall be clearly labeled as such.

(4)(a) Closed door pharmacy products and medical cannabis processor cannabis shall be stored in separate secure rooms that are not accessible from the other licensed facility.

(b) Final product, raw material, or processed material in inventory at the processor shall not travel through the closed door pharmacy area.

(5) Upon request, the licensee shall inform the department of how separation of materials is implemented, including the facility's separation procedures for raw material, extract, and final products.

R66-10-8. Security Standards.

(1) A closed door medical cannabis pharmacy shall comply with security standards established in Section 4-41a-1101 and this rule.

(2) A closed door medical cannabis pharmacy shall have security equipment sufficient to deter and prevent unauthorized entrance into the closed door medical cannabis pharmacy that includes equipment required in this section.

(3) A closed door medical cannabis pharmacy shall be equipped with a secure lock on the entrance to the medical cannabis closed door pharmacy.

(4) A closed door medical cannabis pharmacy shall have electronic monitoring including:

(a) at least one 19-inch or greater call-up monitor;

(b) a printer, capable of immediately producing a clear still photo from any video camera image;

(c) video cameras that:

(i) have a recording resolution of at least 640 x 470, or the equivalent;;

(ii) provide coverage of the single entrance to and exits from the building;

(iii) are capable of identifying any activity occurring in or adjacent to the closed door medical cannabis pharmacy building;

(iv) record continuously, 24 hours a day, 7 days a week or are motion activated;

(v) record at each product packaging and product destruction or disposal location; and

(vi) will allow for the identification of a medical cannabis visitor or closed door pharmacy employee;

(d) a method for storing recordings from the video camera for at least 45 calendar days:

(i) a surveillance system storage device used for locally stored footage shall be secured in the facility in a lock box, cabinet, closet, or secured in another manner, to protect from employee tampering or criminal theft; and

(ii) access to footage stored on a remote server shall be restricted to protect from employee tampering;

(e) a failure notification system that provides an audible and visual notification of failure in the electronic monitoring system;

(f) sufficient battery backup for the video camera and recording equipment to support recording in the event of a power outage;

(g) a date and time stamp embedded on video camera recordings that is set correctly; and

(5) Security measures implemented by a closed door medical cannabis pharmacy to deter and prevent unauthorized entrance or theft of products and to ensure the safety of employees, shall include measures to:

(a) store medical cannabis products and medical cannabis devices in a secure locked limited access area in a manner as to prevent diversion, theft, and loss;

(b) keep safes, vaults, and any other equipment or areas used for storage, including before disposal of the product, securely locked and protected during times other than the time required to remove or replace medical cannabis product or medical cannabis devices;

(c) keep locks and security equipment in good working order and document that equipment is functioning properly at least two times per calendar year;

(d) prohibit keys from being left in locks, stored, or placed in a location accessible to any person other than specifically authorized personnel;

(e) prohibit accessibility to any person other than specifically authorized personnel;

(f) ensure that the outside perimeter of the building is sufficiently lit to facilitate surveillance;

(g) ensure that medical cannabis products and medical cannabis devices are kept out of plain sight and are not visible from a public place; and

(h) secure each product following any instance of diversion, theft, or loss of product, and conduct an assessment to determine whether additional safeguards are necessary.

(6)(a) While inside the closed door medical cannabis pharmacy, each employee shall wear an identification tag or similar form of identification.

(b) The tag shall list the employees' position at the closed door medical cannabis pharmacy as a PMP or pharmacy agent.

(c) A PMP shall carry their registration card when:
(i) they are on the premises of a closed door medical cannabis pharmacy; and
(ii) they are transporting a cannabis product in a medicinal dosage form, or a medical cannabis device.

(7) A closed door medical cannabis pharmacy shall keep and maintain a log showing:

- (a) the full name of each visitor entering the facility;
- (b) the badge number issued;
- (c) the date and time of arrival;
- (d) the date and time of departure; and
- (e) the purpose of the visit.

(8) The visitor log shall be maintained by the closed door medical cannabis pharmacy for a minimum of one year.

(9) The closed door medical cannabis pharmacy shall make the visitor log available to the department upon request.

(10) Only a PMP or a pharmacy agent shall have access to the closed door medical cannabis pharmacy when the closed door pharmacy is closed.

(11) The closed door medical cannabis pharmacy, or parent company, shall maintain a record of not less than five years of the names and work schedules of each PMP or pharmacy agent that has worked at the facility.

R66-10-9. Inventory.

(1) A closed door medical cannabis pharmacy shall inventory and store medical cannabis products and medical cannabis devices:

(a) in a manner to permit clear identification, separation, and easy retrieval of a product; and

(b) in an environment necessary to maintain the integrity of product inventory.

(2) A closed door medical cannabis pharmacy shall use the Inventory Control System (ICS) to establish a record of each transaction, sale, return, and disposal.

(3) A closed door medical cannabis pharmacy shall input information regarding the purchase of medical cannabis products or medical cannabis devices into the ICS immediately following each transaction.

(4) A closed door medical cannabis pharmacy shall :

(a) establish and document inventory controls of medical cannabis product and medical cannabis devices to help the pharmacy detect any diversion, theft, or loss of product in a timely manner;

(b) record inventory findings;

(c) keep records for five years; and

(d) make records available for inspection by the department.

(5)(a) A PMP at each closed door medical cannabis pharmacy shall conduct an inventory audit that includes a reconciliation of each medical cannabis product and medical cannabis device stored at the closed door pharmacy with the pharmacy's inventory record in the ICS.

(b) Pharmacy agents may assist a PMP with the inventory.

(c) An inventory audit shall include:

(i) the time and date of completing the inventory;

(ii) a summary of the inventory findings; and

(iii) the name and signature or initials of the PMP who conducted the inventory.

(6) If a closed door medical cannabis pharmacy employee identifies a reduction in the number of medical cannabis products or medical cannabis devices in their inventory that is not due to a documented cause, the pharmacy shall immediately:

(a) determine where the loss occurred and take and document corrective action;

(b) inform the department of the loss; and

(c) provide the corrective action taken within two business days after the discovery of the loss.

(7) If a reduction in the number of medical cannabis products or medical cannabis devices in the inventory is due to actual or suspected criminal activity, the closed door medical cannabis pharmacy shall immediately make a written report identifying the circumstances surrounding the reduction to:

(a) the department; and

(b) to law enforcement with jurisdiction where the criminal acts occurred.

(8) If a closed door medical cannabis pharmacy employee identifies an increase in the amount of medical cannabis products or medical cannabis devices in the inventory not due to documented causes, the closed door pharmacy shall determine where the increase occurred and take and document corrective action.

(9)(a) The PIC shall conduct and complete an annual comprehensive inventory of products at a closed door medical cannabis pharmacy within 72 hours or three working days of the closed door pharmacy's first annual comprehensive inventory.

(b) The annual comprehensive inventory shall include:

(i) the time and date of the inventory;

(ii) a summary of the inventory findings; and

(iii) the name and signature or initials of the PIC who conducted the inventory.

(10) The closed door medical cannabis pharmacy shall keep records of each ~~daily~~ inventory **audit** and comprehensive annual inventory for five years.

(11)(a) Inventory records may be electronic or physical.

(b) If physical records are kept, the physical records shall be located at the closed door medical cannabis pharmacy where the medical cannabis products and medical cannabis devices are located.

(c) If a closed door medical cannabis pharmacy intends to maintain records at a location other than the closed door pharmacy, they may send a written request to the department that contains:

- (i) the closed door medical cannabis pharmacy name and license number; and
 - (ii) the name and address of the alternate location.
- (d) The department shall approve or deny the request through written notification.
- (e) A copy of the department's approval shall be maintained by the closed door medical cannabis pharmacy.
- (f) The alternate location shall be secured and accessible only to authorized medical cannabis pharmacy employees.

(12) Upon request, a closed door medical cannabis pharmacy shall provide any documentation required to be maintained in this rule to the department for review.

R66-10-10. Transportation.

(1) Transport of medical cannabis from a medical cannabis pharmacy to another location may occur only when:

(a) a home delivery medical cannabis pharmacy is delivering shipments of medical cannabis or medical cannabis devices to a cardholder's:

- (i) home address,
- (ii) caregiver facility, or
- (iii) an address designated by the card holder defined under 4-41a-102 (23);

(b) a medical cannabis pharmacy is transporting medical cannabis or a medical cannabis device from a medical cannabis pharmacy facility to a medical cannabis closed door pharmacy;

(c) a medical cannabis pharmacy or cannabis production establishment is transporting medical cannabis or a medical cannabis device from a medical cannabis pharmacy facility to a cannabis production establishment facility or waste disposal location to be disposed of; or

(d) a product recall is initiated and medical cannabis or a medical cannabis device must be returned from a medical cannabis pharmacy to the cannabis production establishment.

(2) Medical cannabis product and medical cannabis devices to be returned to a cannabis production establishment shall be:

- (a) logged into the ICS;
- (b) stored in a locked container with clear and bold lettering: "Return"; and
- (c) prepared for return as outlined in the approved operating plan of the cannabis production establishment for collecting, storing, and labeling a returned product.

(3)(a) A printed transport manifest shall accompany each transport of cannabis.

(b) The manifest shall contain the following information:

- (i) the address and license number of the departure location;
- (ii) physical address and license number of the receiving location;
- (iii) strain name, quantities by weight, and unique identification numbers of each cannabis material to be transported;

- (iv) date and time of departure;
 - (v) estimated date and time of arrival; and
 - (vi) name and signature of each agent accompanying the cannabis.
- (4) A PMP or pharmacy agent accepting a shipment of medical cannabis or medical cannabis device at a closed door medical cannabis pharmacy shall:
- (a) be given a copy of the transport manifest from the cannabis production establishment or medical cannabis pharmacy;
 - (b) ensure that the cannabis material received is as described in the transport manifest and shall:
 - (i) record the amounts received for each strain into the inventory control system; and
 - (ii) document any differences between the quantity specified in the transport manifest and the quantities received in the ICS and report difference to the department;
 - (c) not delete, void, or change information provided on the transport manifest upon arrival at the medical cannabis closed door pharmacy;
 - (d) clearly record on the manifest the unique initial or identification code of the medical cannabis pharmacy employee who compares the received inventory with the transport manifest and the actual date and time of receipt of the medical cannabis product or medical cannabis devices;
 - (e) if a difference between the quantity specified in the transport manifest and the quantity received occurs, document the difference in the ICS; and
 - (f) log in the ICS any change to medical cannabis product or medical cannabis devices that may have occurred while in transport.
- (5) A closed door medical cannabis pharmacy may only receive medical cannabis products in their final packaging.
- (6)(a) A closed door medical cannabis pharmacy may write notes on the manifest to document discrepancies.

R66-10-11. Minimum Requirements for the Storage and Handling of Cannabis.

- (1) Storage areas shall provide adequate lighting, sanitation, temperature, humidity, space, equipment, and security conditions for the storage of cannabis.
- (2) Stored cannabis shall be at least six inches off the ground.
- (3) Cannabis that is outdated, damaged, deteriorated, misbranded or adulterated shall be stored separately by physical barrier until it is destroyed.

R66-10-12. Cannabis Disposal and Waste.

- (1) A closed door medical cannabis pharmacy shall transfer cannabis waste to the medical cannabis home delivery pharmacy location or to a cannabis production establishment licensed by the department for disposal.
- (2) A closed door medical cannabis pharmacy shall:
 - (a) securely lock and store cannabis waste in a container marked “Not for Sale”;

(b) ensure the medical cannabis product is logged in the ICS at the time of disposal with appropriate information including a description of and reason for the disposal;

(c) follow transportation requirements in Section R66-7-9 to ship the cannabis waste to be destroyed.

R66-10-13. Product Recall.

(1) A recall may be initiated by a cannabis production establishment, a medical cannabis pharmacy, or the department.

(2) The closed door medical cannabis pharmacy shall be bypassed and the recall be handled by the home delivery pharmacy according to the pharmacies operating plan and in compliance with Section R66-5-12.

R66-10-14. Partial Filling.

A PMP or pharmacy agent who partially fills a recommendation for a medical cannabis cardholder shall specify in the EVS the following:

- (1) date of partial fill;
- (2) quantity supplied to the cardholder; and
- (3) quantity remaining of the recommendation partially filled.

R66-10-15. Change in Operating Plans.

(1) A medical cannabis pharmacy shall submit a notice, on a form provided by the department, before making any changes to the closed door pharmacy's operating plan.

(2) A medical cannabis pharmacy may not implement changes to the initial approved operating plan without written approval from the department.

(3) The department shall specify the reason for the denial of approval for a change to the operation plan.

R66-10-16. Revenue Reporting.

A medical cannabis home delivery pharmacy who opens a closed door medical cannabis pharmacy shall submit, on a form provided by the department, quarterly reports, that include:

- (1) the total quarterly revenue for the closed door pharmacy;
- (2) total quarterly revenue for each licensed medical cannabis pharmacy owned by the entity; and
- (3) any other information requested by the department.

R66-10-17. Closed Door Pharmacy License and Renewal.

(1) Each closed door medical cannabis pharmacy license shall expire on the same day as the home delivery pharmacy license.

(2)(a) A medical cannabis home delivery pharmacy shall submit a notice of intent to renew the closed door pharmacy with notice of intent to renew the home delivery pharmacy within 30 days of receiving a notice of expiration from the department.

(b) If the intent to renew is not submitted to the department, the licensee may not continue to operate.

(3) If the licensing fee is not paid by the expiration date, the licensee may not continue to operate.

(4) The board may take into consideration significant violations issued in determining license renewals.

R66-10-18. Violations Categories.

(1) Public Safety Violations: \$3,000 - \$5,000 per violation. This category is for violations that present a direct threat to public health or safety including:

(a) cannabis sold to an unlicensed source;

(b) cannabis purchased from an unlicensed source;

(c) refusal to allow inspection;

(d) failure to comply with pharmacist in charge requirements;

(e) failure to maintain required general operating standards;

(f) failure to comply with product recall requirements;

(g) unauthorized personnel on the premises;

(h) permitting criminal conduct on the premises; or

(i) engaging in or permitting a violation of the Title 4, Chapter 41a, Cannabis Production Establishments and Pharmacies which amounts to a public safety violation as described in this subsection.

(2) Regulatory Violations: \$1,000 - \$5,000 per violation. This category is for violations involving this rule and other applicable state rules:

(a) failure to maintain alarm and security systems;

(b) failure to keep and maintain records for at least five years;

(c) failure to maintain traceability;

(d) failure to follow transportation requirements;

(e) failure to follow the waste and disposal requirements;

(f) failure to follow targeted marketing requirements;

(g) failure to follow agent duties and responsibilities requirements; or

(h) engaging in or permitting a violation of Title 4, Chapter 41a, Cannabis Production Establishments and Pharmacies or this rule which amounts to a regulatory violation as described in this subsection;

(3) Licensing Violations: \$500- \$5,000 per violation. This category is for violations involving licensing requirements including:

(a) an unauthorized change to the operating plan;

(b) failure to notify the department of changes to the operating plan;

(c) failure to notify the department of changes to financial or voting interests of greater than 10%;

(d) failure to follow the operating plan as approved by the department;

(e) engaging in or permitting a violation of this rule or Title 4, Chapter 41a, Cannabis Production Establishments and Pharmacies which amounts to a licensing violation as described in this subsection; or

(f) failure to respond to violations.

(4) The department shall calculate penalties based on the level of violation and the adverse effect or potential adverse effect at the time of the incidents giving rise to the violation.

(5) The department may enhance or reduce the penalty based on the seriousness of the violation.

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