

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

R66-5. Medical Cannabis Pharmacy.

R66-5-1. Authority and Purpose.

- (1) Title 4, Chapter 41a, Cannabis Production Establishments and Pharmacies and Subsection 4-2-103(1)(i) authorize this rule.
- (2) This rule establishes operating and licensing standards and requirements applicable to medical cannabis pharmacies and their employees.
- (3) This rule establishes medical cannabis pharmacy agent duties and responsibilities, application procedures, renewal application procedures, and certification standards.

R66-5-2. 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 any type of medical cannabis card or registration card, whichever applies, authorized under Title 26B, Chapter 4, Part 2 Cannabinoid Research and Medical Cannabis.
 - (3) "Cardholder area" means the area of a medical cannabis pharmacy where a product is purchased that is restricted to a medical cannabis cardholder, a medical cannabis pharmacy employee, or another individual authorized by the medical cannabis pharmacy to enter the cardholder area.
 - (4) "Courier agent" means a medical cannabis courier agent.
 - (5) "Department" means the Utah Department of Agriculture and Food.
 - (6) "DHHS" means The Utah Department of Health and Human Services.
 - (7) "Direct supervision" means that a PMP is physically present at a medical cannabis pharmacy facility and immediately available for in-person face-to-face communication with the pharmacy agent.
 - (8) "Educational event" means an organized event:
 - (a) at which a medical cannabis pharmacy distributes, orally presents, or displays educational material; and
 - (b) that may be held either virtually or in-person.
 - (9) "Educational material" means material or content used, displayed, sold, or distributed for an educational purpose by a medical cannabis pharmacy in-person or online in a business or professional capacity. Educational material includes:
 - (a) live or recorded content of an educational event; or
 - (b) any printed educational material such as a placard, poster, fact sheet, book, pamphlet, flyer, or business card.
 - (10) "Limited access area" means an area of a medical cannabis pharmacy where medical cannabis and medical cannabis devices shall be stored that is:
 - (a) a lockable cabinet in a medical cannabis pharmacy facility to which only a pharmacy agent or PMP has access; or
 - (b) an indoor area or room of a medical cannabis pharmacy facility that is separated from the cardholder and public areas of the medical cannabis pharmacy by a physical barrier with suitable locks and an electronic barrier to detect entry doors.
- (1[2]1) "Pharmacy agent" means a medical cannabis pharmacy agent.
- (1[3]2) "PIC" means a pharmacist in charge who oversees the operation and generally supervises a medical cannabis Pharmacy.
- (1[4]3) "PMP" means a medical cannabis pharmacy medical provider that meets the criteria defined in Subsection 4-41a-1101(12).
- (1[5]4) "Public waiting area" means an area of the medical cannabis pharmacy where the public waits for cardholders and cardholders wait for authorization to enter the cardholder area. Non-cardholders and non-employees may be present in this area.
- (1[6]5) "Recreational disposition" means:
 - (a) slang words or phrasing 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.
- (1[7]6) "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.
- (1[8]7) "State electronic verification system" means the same as the term is defined in Section 26B-4-202 and Subsection 4-41a-102(44).
- (1[9]8) "Targeted marketing" means the same as the term is defined in Subsection ~~26B-4-201(55)~~4-41a-102(47).

([20]19) "Utah resident" means an individual who has established a domicile in Utah.

R66-5-3. General Operating Standards.

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

- (a) be well lit, well ventilated, clean, and sanitary;
- (b) maintain a current list of employees working at the medical cannabis pharmacy that:
 - (i) shall include employee name, department registration license classification and license number, registration expiration date, and work schedule; and
 - (ii) be readily retrievable for inspection by the department and may be maintained in paper or electronic Form;

(c) have a counseling area to allow for confidential patient counseling; and
(d) have current and retrievable editions of the following reference publications, in print or electronic format readily available and retrievable to 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.

(2) A medical cannabis pharmacy may not distribute medical cannabis products or medical cannabis devices to a medical cannabis cardholder unless an employee who is a medical cannabis pharmacy medical provider is physically present and immediately available in the medical cannabis pharmacy.

(3) A medical cannabis pharmacy location shall be open for a cardholder to buy a medical cannabis product and medical devices for a minimum of 35 hours a week, except as authorized by the department.

(4) A medical cannabis pharmacy that closes during normal hours of operation shall implement procedures to notify cardholders when the medical cannabis pharmacy will resume normal hours of operation. Procedures may include telephone system messages and conspicuously posted signs.

(5) Deliveries from a cannabis processing facility or another medical cannabis pharmacy shall be carried out under the direct supervision of a PMP or pharmacy agent, who shall be present to accept the delivery. Upon delivery, the medical cannabis product or medical cannabis devices shall immediately be placed in a limited access area of the medical cannabis pharmacy.

(6) A medical cannabis pharmacy shall protect, at all times, 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.

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

(8) A medical cannabis pharmacy license cannot be assigned or transferred but a licensee may make changes to its ownership or company structure. Any changes to a pharmacy's ownership or company structure shall be reported to the department no later than ten calendar days before the change is to take place. When making a change to its ownership, a licensee may not:

- (a) make an ownership change by an interest of 2% or more without notification of the department at least 10 days before the date of the change; and
- (b) make an ownership change by an interest of 50% or more without applying to the department and receiving department approval and payment of the fee authorized under Subsection 4-41a-1001(3)(c) that the department sets in accordance with Section 63J-1-504.

(9) When applying to the department for approval of an ownership change of more than 50%, the medical cannabis pharmacy shall submit to the department:

- (a) a complete application form;
- (b) payment of an application fee that covers the cost of the application review;
- (c) a description of how the medical cannabis pharmacy shall maintain its compliance with the minimum standards for licensure and operation of the medical cannabis pharmacy; and
- (d) the results of any formal investigation, charge, claim, or adverse action taken against the new owners or individuals with formal financial or management control who make up the new owners, during the past seven years, by any licensing jurisdiction, government agency, law enforcement agency, or court in any state.

(10) A medical cannabis pharmacy shall provide a copy of a certificate of analysis for a medical cannabis product to a medical cannabis cardholder or a recommending medical provider if:

- (a) it is requested in writing; and
- (b) the requestor signs a non-disclosure agreement upon request by the medical cannabis pharmacy.

(11) A medical cannabis pharmacy may be located in the same building as a medical clinic that offers medical cannabis evaluations under the following conditions:

- (a) the building owner may not be the medical cannabis pharmacy or an owner, director, board member, employee, or agent of the medical cannabis pharmacy; and
- (b) the two businesses cannot share an outdoor entrance unless the entrance leads to a common area shared by multiple tenants of the building where the two businesses have separate facility entrances to facility reception areas separated by walls and

locked doors.

R66-5-4. Operating Plan.

(1) A medical cannabis pharmacy license application shall include an operating plan that includes, at a minimum the following:

- (a) the information requested in the application;
- (b) the information listed in Section 4-41a-1004; and
- (c) 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~~
- (iii) procedures for a PIC to determine the pharmacy's medical cannabis inventory under Subsection 4-41a-1101(12).

(2) The department may require the applicant for a medical cannabis pharmacy license to make a change to its operating plan before issuing a pharmacy license. 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 medical cannabis pharmacy's operating plan is subject to the approval of the department. A medical cannabis pharmacy shall submit a notice, in a manner determined by the Department, at least 14 days before the date that it plans to implement any change to its operating plan.

R66-5-5. Pharmacist-In-Charge.

(1) A medical cannabis pharmacy's pharmacist-in-charge (PIC) shall have the responsibility to oversee the medical cannabis pharmacy's operation. The PIC shall generally supervise the medical cannabis pharmacy, though the PIC is not required to be on-site during business hours.

(2) A unique email address shall be established by the PIC, or responsible party, for the medical cannabis pharmacy to be used for official notices, self-audits, or medical cannabis pharmacy alerts initiated by the department.

(a) The PIC or responsible party shall notify the department of the medical cannabis pharmacy's email address in the initial application for licensure. This email address shall not be used to transmit any patient information.

(b) in regard to the unique email address used for self-audits or medical cannabis pharmacy alerts, the PIC or responsible party shall ensure that:

- (i) the medical cannabis pharmacy uses a single email address; and
- (ii) the medical cannabis pharmacy notifies the department of any change in the email address

within seven calendar days of the change.

(3) The ~~[duties of the]~~ PIC shall ~~[include]~~:

(a) ensure that PMPs and pharmacy agents appropriately interpret and distribute a recommendation from a recommending medical provider in a suitable container appropriately labeled for administration or use by a patient;

(b) determine the medical cannabis pharmacy's inventory of medical cannabis and medical cannabis products;

~~[(b)c]~~ ensure that medical cannabis products and medical cannabis devices are distributed safely and accurately with correct dosing guidelines and directions of use as recommended by a recommending medical provider;

~~[(f)d]~~ ensure that PMPs and pharmacy agents communicate to a cardholder, at their request, information concerning any medical cannabis product or medical cannabis devices distributed to the cardholder;

~~[(d)e]~~ ensure that medical cannabis pharmacy personnel receive necessary education and training;

~~[(e)f]~~ establish policies for procurement of medical cannabis products, medical cannabis devices, and educational material sold at the facility;

~~[(f)g]~~ distribute and dispose of medical cannabis products and medical cannabis devices from a medical cannabis pharmacy;

~~[(g)h]~~ ensure appropriate storage of medical cannabis products and medical cannabis devices;

~~[(h)i]~~ maintain a complete and accurate record of products and transactions of the medical cannabis pharmacy necessary to maintain accurate control and accountability for materials required by applicable state laws;

~~[(i)j]~~ establish effective control against theft or diversion of medical cannabis products or medical cannabis devices, and

record of the product;

~~[(j)k]~~ ensure legal operation of the medical cannabis pharmacy, including inspections, and other requirements, of state

law;

~~[(k)l]~~ implement an ongoing quality assurance program that monitors the performance of the personnel at the medical cannabis pharmacy;

~~[(l)m]~~ ensure that the point-of-sale (POS) is in working order;

~~[(m)n]~~ ensure that relevant information is submitted to the state's Inventory Control System and Electronic Verification System in a timely manner;

~~[(n)o]~~ ensure that medical cannabis pharmacy personnel have appropriate licensure and registration;

~~[(o)p]~~ ensure that no medical cannabis pharmacy operates with a ratio of PMPs to pharmacy agents that results in, or reasonably would be expected to result in, a reasonable risk of harm to public health, safety, and welfare; and

(~~p~~g) ensure that the PIC assigned to the medical cannabis pharmacy is recorded with the department, and the department is notified of a PIC change within 14 days of the change or within 24 hours of an immediate change in a PIC's employment status in case of sudden resignation, termination, or emergency leave.

(4) A PMP cannot be designated as PIC for more than two medical cannabis pharmacies at one time.

R66-5-6. Supervision.

(1) A medical cannabis pharmacy licensee shall ensure that the pharmacy is always under the full and actual charge of the medical cannabis pharmacy's PIC as well as under the direct supervision of at least one supervising PMP, who is physically present when a medical cannabis pharmacy is open to the public.

(2) A medical cannabis pharmacy PIC is not required to be in the medical cannabis pharmacy at all times but shall be available for contact within a reasonable period with the supervising PMP.

R66-5-7. Security Standards.

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

(2) A medical cannabis pharmacy shall have security equipment sufficient to deter and prevent unauthorized entrance into a limited access area of the medical cannabis pharmacy that includes equipment required in this section.

(3) A medical cannabis pharmacy shall have a system to detect unauthorized intrusion, which may include a signal system interconnected with a radio frequency method, such as cellular or private radio signals, or another mechanical or electronic device.

(4) A medical cannabis pharmacy shall be equipped with a secure lock on any entrance to the medical cannabis pharmacy.

(5) A 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) a video camera with a recording resolution of at least 640 x 470, or the equivalent, that provides coverage of entrances to and exits from limited access areas, entrances to and exits from the building, and is capable of identifying any activity occurring in or adjacent to the building;

(d) a video camera that records continuously, 24 hours a day, 7 days a week or be motion activated;

(e) a video camera at each point-of-sale and product destruction or disposal location that will allow for the identification of a medical cannabis cardholder, visitor, or pharmacy employee;

(f) a method for storing video 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;

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

(h) sufficient battery backup for a video camera and recording equipment to support [~~at least five minutes of~~] recording in the event of a power outage;

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

(j) a panic alarm in the interior of the facility that is a silent security alarm system signal generated by the manual activation of a device intended to signal a robbery in progress.

(6) Security measures implemented by a medical cannabis pharmacy to deter and prevent unauthorized entrance in areas containing products or theft of products and to ensure the safety of employees and cardholders, 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;

(~~e~~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 a product or medical cannabis devices;

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

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

(~~f~~e) prohibit accessibility of security measures such as combination numbers, passwords, or electronic, or biometric security systems, to any person other than specifically authorized personnel;

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

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

(~~i~~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;

(j) ensure safe cash handling and cash transportation to prevent theft, loss, and associated risk to the safety of employees, customers, and the general public at any medical cannabis pharmacy where a cash transaction is conducted; and
(k) prevent an individual from remaining on the premise of the medical cannabis pharmacy if they are not engaging in activity permitted by Title 26B, Chapter 4, Part 2 Cannabinoid Research and Medical Cannabis or Title 4, Chapter 41a, Medical Cannabis Production Establishments and Pharmacies.

(7) Notwithstanding Subsection R68-40-7(6)(a), a medical cannabis pharmacy may display, in a securely locked case, a sample of each product offered:

(i) the display case shall be transparent; and
(ii) an authorized PMP or pharmacy agent may remove an example of medical cannabis or a medical cannabis device, from the case and provide it to a cardholder for inspection, provided:

(A) the patient does not consume or otherwise use the sample;
(B) the processor label from the original product container or an image showing the processor label is affixed to the sample's container with the unique identifying number that links the medical cannabis product to the ICS; and
(C) the medical cannabis product is destroyed in compliance with applicable laws and the pharmacy's standard operating procedures.

(8) Inside the medical cannabis pharmacy, medical cannabis product and medical cannabis devices, shall be stored in a limited access area during non-business hours.

(9)(a) While inside the medical cannabis pharmacy, each employee shall wear an identification tag or similar form of identification, to clearly identify them to the public. The tag shall list their position at the medical cannabis pharmacy as a PMP or pharmacy agent.

(b) A medical cannabis PMP shall carry their Pharmacy Medical Provider registration card at all times when:
(i) they are on the premises of a medical cannabis pharmacy; and
(ii) they are transporting cannabis in a medicinal dosage form, a cannabis product in a medicinal dosage form, or a medical cannabis device between a cannabis production establishment and a medical cannabis pharmacy.

(10) A medical cannabis pharmacy shall include the following areas of security:

- (a) public waiting area;
- (b) cardholder-only area; and
- (c) limited access area.

(11) A medical cannabis pharmacy shall allow only a medical [α] cannabis cardholder, PMP, pharmacy agent, authorized vendor, contractor, or visitor, to have access to the cardholder area of the medical cannabis pharmacy.

(12) An outside vendor, contractor, or a visitor shall get a visitor identification badge before entering the cardholder-only, or limited access area of a medical cannabis pharmacy. The badge shall be worn at all times when on the premise of the medical cannabis pharmacy and the visitor shall be escorted at all times by an employee authorized to enter the medical cannabis pharmacy.

(a) A visitor must be logged in and out and that log shall be available for inspection by the department.

(b) Each visitor shall return their badge to the medical cannabis pharmacy upon exit.

(13) A 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.

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

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

(13) Product inside a medical cannabis pharmacy shall be kept in a limited access area, inaccessible to any person other than a PMP, pharmacy agent, state employee, or an individual authorized by the medical cannabis pharmacy's PIC. The limited access area shall be identified by the posting of a sign, that shall be a minimum of 12" x 12", and states: "Limited Access Area," in lettering no smaller than one inch in height.

~~(14)~~ (15) If a cabinet or drawer is used as a limited access area, it is not required to have a "Limited Access Area" sign on it.

~~(15)~~ (16) Only a PMP or a pharmacy agent shall have access to the medical cannabis pharmacy when the medical cannabis pharmacy is closed to the public.

~~(16)~~ (17) The medical cannabis pharmacy, or parent company, shall maintain a record of not less than five years of the initials or identification codes that identify each PMP or pharmacy agent by name. The initial or identification code shall be unique, to ensure that each PMP or pharmacy agent can be identified. An identical initial or identification code may not be used for two or more PMPs or pharmacy agents.

R66-5-8. Inventory.

(1) A medical cannabis pharmacy shall be equipped to ensure inventory and storage of medical cannabis products and medical cannabis devices in a manner to permit clear identification, separation, and easy retrieval of a product; and an environment necessary to maintain the integrity of product inventory.

(2) A medical cannabis pharmacy shall use the state's ICS to establish a record of each transaction, sale, return, and disposal.

(3) A medical cannabis pharmacy shall input in the ICS information regarding the purchase of medical cannabis products or medical cannabis devices immediately after a transaction with a cardholder is closed.

(4) A medical cannabis pharmacy shall establish and document daily and weekly 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.

(5) A PMP at each medical cannabis pharmacy shall conduct a monthly inventory that shall include a reconciliation of each medical cannabis product and medical cannabis device stored at the pharmacy with the pharmacy's inventory record in the ICS. Pharmacy agents may assist a PMP with the monthly inventory. A monthly inventory shall include:

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

(b) a summary of the inventory findings; and

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

(6) If a 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 documented causes, the medical cannabis pharmacy shall:

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

(b) immediately inform the department of the loss by telephone; and

(c) provide written notice of the loss and the corrective action taken to the department within two business days after the first 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 criminal activity or suspected criminal activity, the medical cannabis pharmacy shall immediately make a written report identifying the circumstances surrounding the reduction to the department and to law enforcement with jurisdiction where the suspected criminal acts occurred.

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

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

(a) the time and date of the inventory;

(b) a summary of the inventory findings; and

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

(10) Records of each monthly inventory and comprehensive annual inventory shall be kept by the medical cannabis pharmacy for a period of five years.

(11) Inventory records may be electronic or physical. If physical records are kept, the physical records shall be located at the medical cannabis pharmacy where the medical cannabis products and medical cannabis devices are located.

(a) A medical cannabis pharmacy intending to maintain records at a location other than the medical cannabis pharmacy must first send a written request to the department. The request shall contain:

(i) the medical cannabis pharmacy name and license number; and

(ii) the name and address of the alternate location.

(b) The department shall send written notification to the medical cannabis pharmacy documenting the approval or denial of the request.

(c) A copy of the department's approval shall be maintained by the medical cannabis pharmacy.

(d) An alternate location shall be secured and accessible only to authorized medical cannabis pharmacy employees.

(1[+]2) A medical cannabis pharmacy shall provide any documentation required to be maintained in this rule to the department for review upon request.

R66-5-9. Transportation.

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

(a) a home delivery medical cannabis pharmacy is delivering shipments of medical cannabis or medical cannabis devices to a cardholder's home address or caregiver facility;

(b) 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

(c) 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 the 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 in compliance with any guideline and protocol 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 cannabis pharmacy 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.

~~(3)4~~A PMP or pharmacy agent accepting a shipment of medical cannabis or medical cannabis device at a medical cannabis pharmacy facility from a cannabis production establishment 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 inventory control system and report difference to the department;

~~[get a copy of the transport manifest and safeguard the manifest for recordkeeping];~~

~~(b) [not delete, void, or change information provided on the transport manifest upon arrival at the medical cannabis pharmacy;~~

~~[(c) ensure that the medical cannabis product and medical cannabis devices received from a cannabis production establishment are as described in the transport manifest and record the amount received into the ICS;]~~

(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 medical cannabis pharmacy may only receive medical cannabis products in their final packaging.

(6)(a) A medical cannabis pharmacy may write notes on the manifest to document discrepancies.

(b) A medical cannabis pharmacy may reject a shipment from a cannabis processing establishment.

R66-5-11. 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 shall be stored away from other chemicals, lubricants, pesticides, fertilizers, or other potential

Contaminants.

(4) Cannabis that is outdated, damaged, deteriorated, misbranded, adulterated shall be stored separately by physical barrier until it is destroyed.

R66-5-1|+2. Cannabis Disposal and Waste.

(1) A medical cannabis pharmacy's cannabis waste may be disposed of at either a medical cannabis pharmacy location or a location of a cannabis production establishment, licensed by the department.

(2) In addition to complying with standards for cannabis disposal and waste established in Subsection 4-41a-1101(11), a medical cannabis pharmacy shall ensure compliance with the following standards when handling cannabis waste:

(a) designate a location in the limited access area of the medical cannabis pharmacy where cannabis waste shall be securely locked and stored;

(b) designate a lockable container, or containers, that are clearly and boldly labeled with the words "Not for Sale or Use";

(c) ensure logging of the medical cannabis product in the ICS at the time of disposal with appropriate information including:

(i) a description of and reason for the medical cannabis product being disposed of;

(ii) date of disposal;

(iii) method of disposal; and

(iv) name and registration identification number of the agent responsible for the disposal;

(d) wastewater generated during the cannabis waste disposal process shall be disposed of in compliance with applicable state laws and rules;

(e) cannabis waste generated from the cannabis plant, trim, and leaves is not considered hazardous waste unless it has

been treated or contaminated with a solvent or pesticide;

(f) cannabis waste disposed of shall be made unusable;

(g) cannabis waste, which is not designated as hazardous shall be made unusable by grinding and incorporating the cannabis waste with other ground materials so the resulting mixture is at least 50% non-cannabis waste by volume or other methods approved by the department; and

(h) materials used to grind and incorporate with cannabis may be compostable or non-compostable;

(i) compostable waste is cannabis waste to be disposed of as compost or in another organic waste method mixed with:

(A) food waste;

(B) yard waste; or

(C) vegetable-based grease or oils;

(ii) compostable waste is cannabis waste to be disposed of in a landfill or another disposal method, such as incineration, mixed with:

(A) paper waste;

(B) cardboard waste;

(C) plastic waste; or

(D) soil.

R66-5-1[2]3. Product Recall.

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

(2) A medical cannabis pharmacy shall maintain a recall plan that includes, at a minimum:

(a) a designation of at least one employee who shall serve as the recall coordinator;

(b) if the recall is initiated by a medical cannabis pharmacy, a requirement that the pharmacy will provide immediate notification to the department and the cannabis production establishment from which it obtained the cannabis product in question;

(i) a requirement that notification shall occur within 24 hours of the pharmacy becoming aware of a complaint about the medical cannabis product or medical cannabis device;

(c) a procedure for identifying and isolating recalled product to prevent or minimize distribution to patients;

(d) a procedure to retrieve and destroy recalled product; and

(e) a communication plan to notify those affected by the recall.

(3) The medical cannabis pharmacy shall track the total amount of affected medical cannabis product and the amount of medical cannabis product returned to the medical cannabis pharmacy as part of the recall.

(4) The medical cannabis pharmacy shall coordinate the destruction of the medical cannabis product with the department and allow the department to oversee the destruction of the final product.

(5) A medical cannabis pharmacy shall notify the department before initiating a voluntary recall.

R66-5-1[3]4. Partial Filling.

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

(1) date of partial fill;

(2) quantity supplied to the cardholder; and

(3) quantity remaining of the recommendation partially filled.

R66-5-1[4]5. Closing a Pharmacy.

(1) At least 14 days before the closing of a medical cannabis pharmacy, the PIC shall:

(a) send written notice to the department containing the name, address, and department issued license number of the medical cannabis pharmacy;

(b) surrender the license issued to the medical cannabis pharmacy;

(c) provide a statement to the department attesting:

(i) a comprehensive inventory was conducted;

(ii) the manner in which the medical cannabis product and medical cannabis devices will be transferred or disposed of;

(iii) the anticipated date of closing;

(iv) the name, address, and department issued license number of the medical cannabis pharmacy or cannabis production establishment acquiring the medical cannabis and medical cannabis devices from the medical cannabis pharmacy that is closing;

(v) the date of transfer when the medical cannabis product and medical cannabis devices will occur; and

(vi) the name and address of the medical cannabis pharmacy to which the orders, including any refill information and patient records, will be transferred; and

(e)d post a closing notice in a conspicuous place at the public entrance doors to the medical cannabis pharmacy that includes the closing date.

(2) If the medical cannabis pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or emergency circumstances, and the PIC cannot provide notification 14 days before the closing, the PIC shall provide notification to the department of the closing, no later than 24 hours after the closing.

(3) If the PIC is not available to comply with the requirements of this section, the owner or legal representative shall be

responsible for compliance with this section.

(4) On the date of the closing, the PIC shall remove medical cannabis product and medical cannabis devices from the medical cannabis pharmacy by one or a combination of the following methods:

(a) transport them to a cannabis processing facility for credit or disposal; or
(b) transfer or sell them to a person who is legally entitled to have medical cannabis products and medical cannabis devices, such as another medical cannabis pharmacy in Utah.

(5) The PIC shall remove signs and notify the landlord of the property that it is unlawful to use the word "medical cannabis pharmacy," or any other word or combination of words of the same or similar meaning or any graphic representation that would mislead or tend to mislead the public that a medical cannabis pharmacy is located at the address.

R66-5-1[5]6. Abandonment of a License.

A medical cannabis pharmacy shall be considered to have abandoned their license if they fail to begin operations within one year after the day on which the department issues an intent to award a medical cannabis pharmacy license.

R66-5-1[6]7. Walk-up, Drive-Thru, and Curbside Service.

(1) A medical cannabis cardholder may contact a medical cannabis pharmacy by phone or online before the time of walk-up, drive-thru, or curbside service pick-up to make an order.

(2) A medical cannabis cardholder transaction may take place outside the medical cannabis pharmacy facility, but it shall still occur within the total property boundary of the licensed entity. Walk-up, drive-thru, and curbside service transactions shall occur at a licensed location that is owned, leased, or rented by the licensed entity and shall not occur on a public sidewalk or an adjacent parking lot.

(3) If a product is bought with cash, the cash must be taken into the medical cannabis pharmacy facility after each transaction. If a medical cannabis pharmacy obtains approval from the Division of Finance to accept customer payments through an electronic payment provider, a medical cannabis cardholder using walk-up, drive-thru, and curbside pick-up service may make payments using the approved electronic payment provider.

(4) Medical cannabis products and medical cannabis devices, including those that are awaiting pick-up, shall be securely stored in the medical cannabis pharmacy facility until a medical cannabis cardholder arrives for pick-up. Under no circumstances may a medical cannabis product or medical cannabis device be stored outside of a medical cannabis pharmacy facility before a customer arrives to pick-up the product.

(5) A medical cannabis pharmacy's video surveillance shall enable the video recording of each medical cannabis cardholder transaction. This includes video surveillance of a cardholder, cardholder vehicle, medical cannabis pharmacy employee verifying the cardholder's valid form of government issued identification, and the transfer and dispensing of an item bought by a cardholder. Video cameras shall record points of entry and exit of a parking lot and shall be angled to ensure the capture of clear and certain identification of a cardholder and their vehicle's license plate.

(6) The individual receiving the delivery of a product from the medical cannabis pharmacy employee via walk-up, drive-thru or curbside pick-up shall be a cardholder. When drive-thru service is used, the medical cannabis cardholder verifying their ID to the medical cannabis pharmacy shall be visible to cameras and to the medical cannabis pharmacy employee who is helping them.

(7) Children under age 18 may be present in a vehicle that arrives for drive-thru or curbside pick-up service.

(8) When a PMP's consultation with a medical cannabis cardholder is required, the consultation may be provided in-person, over the phone, or with another real-time communications device. It is the responsibility of the medical cannabis pharmacy to ensure the privacy of these consultations regardless of where or how the consultations happen.

(9) When a medical cannabis pharmacy employee transports a container of medical cannabis product to a medical cannabis cardholder via walk-up, drive-thru, or curbside service, the container shall be contained within a box or an opaque bag.

(10) When drive-thru service is used, a medical cannabis pharmacy may use a secure drive-thru drawer or pneumatic tube to transport medical cannabis product, medical cannabis device, educational materials, valid photo identification, cash, and documents between a medical cannabis pharmacy employee and a medical cannabis cardholder.

R66-5-1[7]8. Targeted Marketing.

(1) A medical cannabis pharmacy may engage in targeted marketing pursuant to Subsection 4-41a-1104(2)(f).

(2) Targeted marketing that makes a statement relating to side effects, consequences, contraindications, and effectiveness shall present a true statement of the information.

(3) Targeted marketing is false, lacking fair balance, or otherwise misleading if it:

(a) contains a representation or suggestion that a cannabis strain, brand, or product is better, more effective, useful in a broader range of conditions or patients or safer than other drugs or treatments including other cannabis strains or products, unless the claim has been demonstrated by substantial evidence or substantial clinical data;

(b) contains favorable information or opinions about a medical cannabis product previously regarded as valid but which have been made invalid by contrary and more credible recent information;

(c) uses a quote or paraphrase out of context or without citing conflicting information from the same source, to convey a false or misleading idea;

(d) uses a study on individuals without a qualifying medical condition without disclosing that the subjects were not suffering from a qualifying medical condition;

- (e) uses data favorable to a medical cannabis product derived from patients treated with a different product or dosages different from those legal in Utah; or
 - (f) contains favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for the information or conclusions.
- (4) Targeted marketing may not include:
- (a) unsubstantiated health claims or other claims that are not supported by substantial evidence or substantial clinical data;
 - (b) claims that cannabis cures any medical condition; or
 - (c) content that has a recreational disposition.
- (5) Notwithstanding the recreational disposition of some cannabis strains and medicinal dosage forms, a medical cannabis pharmacy may reference a cannabis strain or a medicinal dosage form in targeted marketing.
- (6) When posting promotional information about a medical cannabis product for sale online, a medical cannabis pharmacy shall list online the total amount of each cannabinoid contained in the product, measured in milligrams.

R66-5-19. 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 pharmacy's operating plan, including:
- (a) ownership or financial backing of the facility;
 - (b) the facility's name;
 - (c) any modification, remodeling, expansion, reduction, or physical, non-cosmetic alteration of a facility;
 - (d) change to the protected areas; and
 - (e) any other information requested by the department.
- (2) Pursuant to Subsection 4-41a-201.1(7), a medical cannabis pharmacy may not implement changes to the initial approved operation plan without board approval.
- (3) The department shall specify the reason for the denial of approval for a change to the operation plan.

R66-5-20. Pharmacy License and Renewal

- (1) Each cannabis pharmacy license shall expire one calendar year from the date of licensure.
- (2)(a) A medical cannabis pharmacy shall submit a notice of intent to renew to the department 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.

R68-40-[48]21. Criteria and Process for Issuance of Additional Licenses.

- (1) The Department may consider the following factors as criteria when determining if additional medical cannabis pharmacy licenses shall be issued pursuant to Subsection 4-41a-1005(1)(d):
- (a) high potential for growth in the number of medical cannabis card holders located in one or more regions of the State;
 - (b) access to medical cannabis home delivery service in the state or in certain regions of the state;
 - (c) commuting patterns and economic activity in certain regions of the state;
 - (d) the driving distance for medical cannabis cardholders or potential medical cannabis cardholders residing in certain regions of the state from their home to the nearest medical cannabis pharmacy location; or
 - (e) the inadequate supply, quality, or variety of medical cannabis in the state or certain regions of the state.
- (2) As the Department considers one or more factors described in Subsection (1), it shall consult with and consider input from the Utah Department of Health and Human Services, the medical cannabis industry, and the public.
- (3) The Department's process of consultation and consideration of input shall include meetings with stakeholders and holding of a public hearing during which it will accept public comment.
- (4) If the Department determines that an additional medical cannabis pharmacy license should be issued, the Department shall accept applications for the license in accordance with Title 63G, Chapter 6a, Utah Procurement Code.

R66-5-22. Geographic Regions.

- (1) Pursuant to Subsection 4-41a-1005(1), the department shall divide the state into geographic regions based on:
- (a) overall population;
 - (b) patient population; and
 - (c) travel time.
- (2) The department establishes the following geographic regions by county:
- (a) Region 1- Northern Utah:
 - (i) Box Elder;
 - (ii) Cache; and
 - (iii) Rich

- (b) Region 2 - Weber Basin
- (i) Davis;
- (ii) Morgan; and
- (iii) Weber;
- (c) Region 3 - Salt Lake:
- (i) Salt Lake;
- (ii) Summit; and
- (iii) Tooele;
- (d) Region 4 - Uintah Basin:
- (i) Daggett;
- (ii) Duchesne; and
- (iii) Uintah;
- (e) Region 5 - West Central:
- (i) Juab;
- (ii) Sanpete;
- (iii) Utah; and
- (iv) Wasatch;
- (f) Region 6- Central:
- (i) Carbon;
- (ii) Emery;
- (iii) Millard;
- (iv) Piute;
- (v) Sevier; and
- (vi) Wayne;
- (g) Region 7 - Southwest:
- (i) Beaver;
- (ii) Garfield;
- (iii) Iron;
- (iv) Kane; and
- (v) Washington; and
- (h) Region 8 - Southeast:
- (i) Grand; and
- (ii) San Juan.

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R66-5-19]23. Limited Medical Provider Recommendation Form.

(1) A medical cannabis pharmacy may accept and process a completed "Limited Medical Provider Recommendation for Medical Cannabis" form. A pharmacy agent or a PMP employed by a medical cannabis pharmacy may perform a form verification but only a PMP may make changes or additions to a form after documenting verbal or written approval of changes or additions that are communicated by an LMP. An LMP recommendation cannot be entered into the EVS by a PMP or pharmacy agent without a complete DHHS-approved form that is hand-delivered, emailed, or faxed to the medical cannabis pharmacy. When verifying the validity of the form, a medical cannabis pharmacy shall verify:

- (a) the form is complete and no information on the form appears to have been adulterated;
- (b) the suffix of the state-issued professional license number matches specific numbers assigned to the provider's state-issued professional license type;
- (c) there are nine digits in the Drug Enforcement Agency (DEA) license number;
- (d) the clinic name, email address, mailing address, and telephone number appear to be legitimate; and
- (e) with the clinic that an LMP at that clinic completed a form for the patient named in the form.

(2) If the form fails any part of the verification, a PMP shall investigate any missing or incorrect information. If a PMP is initially unable to receive verification of the form from the clinic, the form cannot be processed and the PMP shall continue to contact the clinic to seek verification of the information on the form.

(3) The pharmacy shall maintain a record of the pharmacy employee having received or not received verification of a valid form from the clinic. For hand-delivered and electronically delivered forms, the pharmacy shall upload the form to the patient's EVS account. The verification of the form shall be recorded in the "Medical Cannabis Pharmacy Use Only" at the bottom of the form or in the patient's EVS profile. If a PMP corrected or added information on the form upon order of the LMP, a note documenting the change shall be recorded.

(4) If a form is believed to be fraudulent, a medical cannabis pharmacy shall notify the DHHS in writing via email within 24 hours of the first receipt of the form.

R66-5-2]0]4. Agent Duties and Responsibilities.

- (1) All medical cannabis pharmacy employees shall be registered as PMP or a medical cannabis pharmacy agent.
- (2) A pharmacy agent may perform the following duties:
 - (a) assist a prospective cardholder with an application for a medical cannabis card;

- (b) within the dosing guidelines specified by an RMP or PMP, assist the cardholder with understanding available products, proper use of a medical device, medical cannabis strains, and methods of consumption or application;
 - (c) using the ICS, verify the status of an individual's medical cannabis card, and dosing guidelines in a patient Recommendation;
 - (d) enter and retrieve information from the ICS;
 - (e) authorize entry of a cardholder into the cardholder counseling area;
 - (f) take a refill order from an RMP;
 - (g) provide pricing and product information;
 - (h) accurately process cardholder payment, including the issuance of receipt, refund, credit, and cash;
 - (i) prepare labeling for a product;
 - (j) retrieve medical cannabis, and medical cannabis device, from inventory;
 - (k) accept a new order of medical cannabis, or medical cannabis device, orders left on voicemail for a PMP to review;
 - (l) verbally offer to a cardholder, the opportunity for counseling with a PMP regarding medical cannabis, or a medical cannabis device;
 - (m) assist with dispensing of product to a cardholder;
 - (n) screen calls for a PMP;
 - (o) prepare an inventory of medical cannabis and medical cannabis device;
 - (p) transport medical cannabis, or medical cannabis device; and
 - (q) assist with maintaining a safe, clean, and professional environment.
- (3) A pharmacy agent may not perform the following duties:
- (a) receive dosing guidelines for a patient's recommendation over the phone or in person;
 - (~~e~~)b) determine or modify dosing guidelines in a patient's recommendation; or
 - (~~d~~)c) provide counseling or consultation regarding a patient's medical condition, or medical treatment.

R66-5-2[1]5. Agent Application Procedures.

- (1) The application procedures established in this section shall govern an application for initial issuance of a pharmacy agent registration card, under Title 4, Chapter, 41a, Cannabis Production Establishments and Pharmacies
- (2) Each pharmacy agent card applicant shall apply upon forms available from the department.
- (3) The department may issue a card to an applicant who submits a complete application if the department determines that the applicant meets the card requirements.
- (4) The department shall provide written notice of denial to an applicant who submits a complete application if the department determines that the applicant does not meet the card requirements.
- (5) The department shall provide a written notice to an applicant who submits an incomplete application indicating that ~~the~~ the application is closed unless the applicant corrects the deficiency within the time period specified in the notice and otherwise meets card requirements.
- (6) The written notice of denial or incomplete application shall be sent to the applicant's last email address shown in the EVS database.
- (7) Each applicant shall maintain a current email address with the department. Notice sent to the last email address on file with the department constitutes legal notice.

R66-5-2[2]6. Agent Renewal Application Procedures.

- (1) Renewal application procedures established in the rule shall apply to applicants applying for renewal of a pharmacy agent registration card, under Title 4, Chapter, 41a, Cannabis Production Establishments and Pharmacies.
- (2) Each card applicant shall apply upon renewal application forms available from the department.
- (3) The department shall issue a card to an applicant who submits a complete renewal application if the department determines that the applicant meets the card requirements.
- (4) The department shall provide written notice of denial to an applicant who submits a complete renewal application if the department determines that the applicant does not meet the card requirements.
- (5) The department shall provide written notice of an incomplete application to an applicant who submits an incomplete application. The notice shall advise the applicant that the renewal application is incomplete and closed unless the applicant corrects the deficiency within the time period specified in the notice and otherwise meets card requirements.
- (6) The department shall send a renewal notice to each cardholder before the expiration date shown on the cardholder's card. The notice shall include directions for the cardholder to renew the card via the department's website.
- (7) Renewal notices shall be sent by email to the cardholder's last email shown in the EVS database.
- (8) A renewal notice shall advise each cardholder that a card will automatically expire on the expiration date and will no longer be valid.
- (9) A pharmacy agent shall renew their pharmacy agent registration card with the department within one year of its expiration date. Failure to renew an expired card within one year shall result in the applicant having to submit a new online registration form for a pharmacy agent registration card if they choose to obtain a card again in the future.

R66-5-2[3]7. Continuing Education Requirements.

The certification standard for initial or renewal registration of a pharmacy agent card will be successful completion of a continuing education course regarding state medical cannabis law and patient privacy and federal health information privacy laws that is offered or approved by the department.

R66-5-28. Violation 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, Medical Cannabis Pharmacy Operation and Agents, 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 the walk- up, drive-thru, delivery, and curbside service requirements;
- (g) failure to follow targeted marketing requirements;
- (h) failure to follow agent duties and responsibilities requirements;or
- (i) engaging in or permitting a violation of Title 4, Chapter 41a, Medical Cannabis Pharmacy Operation and Agents 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, Medical Cannabis Pharmacy License 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.

KEY: medical cannabis, medical cannabis pharmacy, marijuana

Date of Last Change: ~~2023~~2024

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