

CERTIFICATION INFORMATION

This information is required to be read and understood by medical cannabis pharmacy agent applicants before registration with the Utah Department of Health (DOH). It is intended to be a general overview of medical cannabis laws pertaining to the practice of a pharmacy agent in Utah and medical cannabis pharmacy best practices. This information only highlights certain sections of the law and it NOT intended to cover all laws applicable to the practice of a pharmacy agents. Applicants are responsible to read and understand all laws pertaining to the registration for which they are applying.

1. QUALIFYING CONDITIONS (26-61A-104)

Individuals with the following conditions are authorized under the Utah Medical Cannabis Act to receive a medical cannabis patient card:

- HIV or acquired immune deficiency syndrome (AIDS)
- Alzheimer's disease
- Amyotrophic lateral sclerosis
- Cancer
- Cachexia
- Persistent nausea that is not significantly responsive to traditional treatment except for nausea related to: pregnancy, cannabis-induced cyclical vomiting syndrome, or cannabinoid hyperemesis syndrome
- Crohn's disease or ulcerative colitis
- Epilepsy or debilitating seizures
- Multiple sclerosis or debilitating muscle spasms
- Post-traumatic stress disorder (PTSD) that is being treated and monitored by a mental health therapist and that: has been diagnosed by a health care provider or mental health provider by the VA and documented in the patient's record; or has been diagnosed or confirmed by evaluation by a psychiatrist, master's level degree psychologist, a master's level degree licensed clinical social worker, or a psych APRN.

- Autism
- Terminal illness when the patient's remaining life expectancy is less than 6 months
- Condition resulting in the individual receiving hospice care
- Rare condition or disease that affects less than 200,000 individuals in the U.S., as defined in federal law and this is not adequately managed despite treatment attempts using conventional medications (other than opioids or opiates) or physical interventions
- Pain lasting longer than two weeks that is not adequately managed, in the qualified medical provider's opinion, despite treatment attempts using conventional medications other than opioids or opiates or physical interventions
- If a patient does not have a qualifying condition specifically named in the law, they may petition the Compassionate Use Board (CUB) for approval of their medical cannabis card. CUB meetings are closed to the public, applicants, and medical providers.

2. QUALIFIED MEDICAL PROVIDERS (26-61A-106)

A qualified medical provider (QMP) is a medical professional who can recommend a patient for treatment with medical cannabis. QMP registration is limited to a Utah licensed:

- Medical Doctor (MD)
- Osteopathic Physician (DO)
- Advanced Practice Registered Nurse (APRN)
- Physician Assistant (PA)
- Must be licensed to prescribe a controlled substance.
- Must complete at least four hours of continuing medical education coursework approved by the (DOH) prior to registration and four hours upon every two-year renewal.
- May not recommend medical cannabis treatment to more than 275 of the QMP's patients at one time, or to more than 600 patients if the QMP is certified by the appropriate American medical board in anesthesiology, neurology, oncology, pain, hospice and palliative medicine, physical medicine and rehabilitation, rheumatology, endocrinology, psychiatry or if a licensed business employs or contracts the QMP for the specific purpose of providing hospice and palliative care.

A QMP may only recommend medical cannabis treatment to a patient in the course of the physician-patient relationship after completing and documenting in the patient's record a thorough assessment of the patient's condition and medical history. A QMP cannot be employed by a medical cannabis pharmacy.

3. QUALIFIED MEDICAL PROVIDER DOSAGE PARAMETERS

If a QMP recommends medical cannabis to a patient without specifying dosage parameters, <u>the dosage parameters will</u> <u>be determined by a pharmacy medical provider (pharmacist, MD, or DO registered with the DOH) at the cardholder's</u> <u>chosen medical cannabis pharmacy</u>. When making this determination, the pharmacy medical provider (PMP) must:

- review pertinent medical records, including the qualified medical provider documentation submitted to the EVS; and
- after completing the review and consulting with the recommending QMP as needed, determine the best course of treatment through consultation with the cardholder regarding:
 - the individual's qualifying condition underlying the recommendation from the qualified medical provider;
 - indications for available treatments;
 - dosing parameters; and
 - potential adverse reactions.

4. DOSAGE FORMS AND DEVICES (26-61A-102, 502)

Medical cannabis will only be available for purchase in Utah in the following forms under the Utah Medical Cannabis Act:

- Tablet
- Capsule
- Concentrated oil
- Sublingual preparation
- Liquid suspension
- Topical preparation
- Transdermal preparation
- Gelatinous cube
- Unprocessed cannabis flower in an opaque, tamper-evident, child-resistant container that contains a quantity that

varies no more than 10% from the stated weight at the time of packaging.

- If patient does not respond to two forms listed above, a qualified medical provider may recommend a wax or resin dosage form.
- Smoking of cannabis is not permitted but patients may purchase a medical cannabis device that warms cannabis material into a vapor without use of a flame and delivers cannabis to an individual's respiratory system.

SMOKING OF MARIJUANA IS PROHIBITED. Edible products (besides gelatinous cubes) such as candies, cookies, brownies, and unprocessed flowers outside of blister packs are not permitted under Utah Code 26-61a-102 (32).

5. MEDICAL CANNABIS CARDS (26-61A-201-205)

Patients who are Utah residents may apply for medical cannabis cards with their qualified medical provider (QMP) through the electronic verification system. The department evaluates applications and issues cards within 15 days if applicant qualifies. All card applications for patients under 21 years of age must be approved by the Compassionate Use Board. Cards issued include the following:

Medical Cannabis Patient Card

- Issued to patients 18 years of age and older
- Valid for up to 90 days upon initial issuance, then six months upon renewal (with additional fee)
- Card for patients age 18-20 must have card approved by Compassionate Use Board

Medical Cannabis Caregiver Card

- Card renews automatically with associated Medical Cannabis Patient or Guardian Card (with additional fee)
- Criminal background check

Provisional Patient Card

- Patients under 18 years of age
- Issued and renews automatically with Guardian Card (no additional fee)
- Requires approval by Compassionate Use Board

Medical Cannabis Guardian Card

- Issued to parent or guardian of patients under 18 years of age
- Valid for 90 days upon initial issuance, then six months upon renewal (with additional fee)
- Criminal background check

In any one 28-day period, a patient may not purchase more than the lesser of:

- An amount sufficient to provide 30 days of treatment based on the dosing parameters that the qualified medical provider (QMP) recommends; or
- 113 grams by weight of unprocessed cannabis (flower); or
- For cannabis products in medicinal dosage form, more than a total of 20 grams of total composite THC.

Medical cannabis cardholders may not possess more than:

- 113 grams by weight of unprocessed cannabis (flower); and
- An amount of cannabis product that contains 20 grams of total composite THC.

7. PHARMACY EMPLOYEE REGISTRATION REQUIREMENTS

Employees of a medical cannabis pharmacy must be registered by the department as either a medical cannabis pharmacy agent or a pharmacy medical provider.

- 1. Pharmacy Medical Provider (PMP). Each medical cannabis pharmacy must employ a Utah licensed pharmacist who is registered by the department as a PMP who is designated as the pharmacy's pharmacist in charge (PIC). A medical cannabis pharmacy may also employ a Utah licensed physician who must register as a PMP. PMP registration expires every two years unless it is renewed by the PMP. A PMP cannot also be registered as a QMP. To register as a PMP, an individual must:
 - a. verify completion of at least 4 hours of continuing education coursework that meets criteria established by the department;
 - b. provide the name and location of the pharmacy where they seek to act as a PMP; and
 - c. pay an application fee;
 - d. be at least 21 years of age.¹
- Pharmacy Agent. A qualified medical provider (QMP) cannot be registered as a pharmacy agent. To be registered as a pharmacy agent, an individual must:
 - pass a national criminal background check by demonstrating that they have not been convicted under state or federal law of a felony or, after December 3, 2018, a misdemeanor for drug distribution.²
 - b. provide the name and location of the pharmacy where they seek to act as an agent;
 - c. pay an application fee;
 - d. comply with a certification standard established by the department (reading and acknowledgment of understanding the information shared in this document fulfills the certification requirement);

¹ Utah Code 26-61a-403

² Utah Code 26-61a-401 (6)

e. be at least 21 years of age.³

8. PHARMACY OPERATING REQUIREMENTS (26-61A-501,502,505)

- **1. Pharmacy Medical Provider (PMP) Onsite.** A medical cannabis pharmacy must have a pharmacy medical provider registered with the DOH physically onsite at the pharmacy facility location at all times when the pharmacy is open.
- 2. Compliance with Operating Plan. A medical cannabis pharmacy must operate solely at the physical address provided to the department and in accordance with the operating plan provided to the department.
- **3.** Notification of Operation Plan Changes. A medical cannabis pharmacy must notify the department before any change in the medical cannabis pharmacy's physical address or operating plan.
- 4. Facility Visitors. An individual may not enter a medical cannabis pharmacy unless the individual is at least 18 years old and possesses a valid pharmacy medical provider card, a medical pharmacy agent card, or a medical cannabis card. Pharmacy visitors who are not registered as a PMP or a pharmacy agent are required to sign in and out upon entrance and exit of the facility, wear a visitor badge at all times, and be escorted by a PMP or pharmacy agent at all times.
- 5. Security. A medical cannabis pharmacy facility must have a single, secure public entrance, a lock on each area where the pharmacy stores cannabis or cannabis product, and a security system with a backup power source that:
 - a. detects and records entry into the medical cannabis pharmacy; and
 - b. provides notice of an unauthorized entry to law enforcement when the pharmacy is closed.
- 6. Purchase Limit Clearly Posted. A medical cannabis pharmacy must post, both clearly and conspicuously in the pharmacy, the limit on the purchase of cannabis described in Utah Code 26-61a-502(2).
- **7.** No Samples. A medical cannabis pharmacy cannot give medical cannabis product samples to cardholders.
- **8.** No Consumption on Property. A medical cannabis pharmacy must prohibit any individual from consuming cannabis product on the property or premises of the pharmacy.

³ Utah Code 26-61a-402 (401)

- **9. Processor Label**. Products sold by pharmacies must have a label on them placed by the processor that:
 - a. clearly displays the amount of total composite THC and CBD in the container;
 - b. has a unique ID number that is connected to the inventory control system and that identifies the manufacturing process the processing facility used to manufacture the cannabis product
 - c. identifies the cannabinoid extraction process that the cannabis processing facility used to create the product;
 - d. does not display an image, word, or phrase that the facility knows or should know appeals to children; and
 - e. discloses each active or potentially active ingredient and possible allergen.⁴
- **10. Pharmacy Label.** A medical cannabis pharmacy cannot sell cannabis or cannabis product unless the product has a label affixed to the container indicating the following minimum information:
 - a. the name, address, and telephone number of the medical cannabis pharmacy;
 - b. the unique identification number that the pharmacy assigns;
 - c. the date of sale;
 - d. the name of the patient;
 - e. the name of the qualified medical provider who recommended the medical cannabis treatment;
 - f. directions for use and cautionary statements, if any;
 - g. the amount dispensed and the cannabinoid content;
 - h. the beyond use date; and
 - i. any other requirements the department determines.⁵
- **11. Counseling.** A PMP or a pharmacy agent must offer each medical cannabis cardholder at the time of purchase the opportunity to receive face to face counseling with the onsite PMP. A medical cannabis pharmacy must provide medical cannabis cardholders a telephone number or website by which the cardholder may contact a pharmacy medical provider (PMP) for counseling. The pharmacy must also do the following:
 - a. If a QMP chooses to <u>not</u> provide dosing parameters in the recommendation, the PMP must:
 - review pertinent medical records, including the QMP's evaluation of the qualifying condition underling the recommendation, a description of prior treatment attempts with cannabis products, and the patient's current medication list; and
 - 2. after completing the review and consulting with the recommending QMP as needed, determine the best course of treatment through consultation with the cardholder regarding the patient's qualifying condition underlying the

⁴ Utah Code 4-41a-602 (1)

⁵ Utah Code 26-61a-501 (10)(b)

recommendation from the QMP, indications for available treatments, dosing parameters, and potential drug and adverse reactions.⁶

- b. If a QMP chooses to provide dosing parameters in the recommendation, the PMP must verbally offer to a medical cannabis cardholder at the time of purchase of a cannabis product or medical cannabis device, personal, face-to-face counseling with the PMP.⁷
- **12.** Advertising. A medical cannabis pharmacy cannot advertise in any medium other than the following:
 - 1. signage outside of the pharmacy that includes only the medical cannabis pharmacy's name and hours of operation and a green cross that does not exceed four feet by five feet in size and complies with local ordinances regulation signage; and
 - 2. a website that includes information about:
 - 1. the location and hours of operation of the pharmacy;
 - 2. a product or service available at the pharmacy;
 - 3. best practices that the pharmacy upholds; and
 - 4. educational material related to the medical use of cannabis.⁸
- **13.** Available Products. A medical cannabis pharmacy cannot sell a product other than:
 - a. cannabis or cannabis product in a medicinal dosage form, or a medical cannabis device that the medical cannabis pharmacy acquired from a cannabis processing facility licensed by UDAF; and
 - b. educational material related to the medical use of cannabis.⁹
- **14.** Dispensing Limits. A pharmacy may not sell in any one 28-day period, more than the lesser of:
 - 1. an amount sufficient to provide 30 days of treatment based on the dosing parameters that the relevant qualified medical provider (QMP) recommends; or
 - 2. 113 grams by weight of unprocessed cannabis that is in a blister pack and that carries a label clearly displaying the amount of THC and CBD in the cannabis; or
 - 3. an amount of cannabis products that is in a medicinal dosage form and that contains, in total, greater than 20 grams of total composite THC.¹⁰
- **15. Product Fees**. The department requires a uniform fee of \$3 on each medical cannabis cardholder transaction in a medical cannabis pharmacy be paid to the department.¹¹
- **16. Product Waste Disposal**. Medical cannabis pharmacies may create a disposal program that allows an individual to deposit unused or excess medical cannabis in a locked box or other secure receptacle within the pharmacy. Medical cannabis pharmacies shall dispose of any deposited medical cannabis by:
 - Rendering the product unusable and unrecognizable before transporting it;

⁶ Utah Code 26-61a-502 (4)

⁷ Utah Code 26-61a-501 (11)

⁸ Utah Code 26-61a-505

⁹ Utah Code 26-61a-502 (1)

¹⁰ Utah Code 26-61a-502 (2)

¹¹ Utah Code 26-61a-502 (8)

- Disposing of the product in accordance with:
 - Federal and state law, rules and regulations related to hazardous waste;
 - The Resource Conservation and Recovery Act;
 - The Solid Waste Management Act; and
 - Other regulations that the department makes in accordance with the Administrative Rulemaking Act.¹²

9. PROTECTION OF PRIVATE INFORMATION

Medical cannabis pharmacy agents must guard the confidentiality of all sensitive identifiable data.

- Sensitive identifiable data includes personally identifiable information (PII) and personal health information. PII is any information that can be used to distinguish an individual's identity, such as name, social security number, date and place of birth, mother's maiden name, or biometric records; and any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information. Sensitive identifiable data may be found in:
 - a. spoken/verbal communications (telephone conversations, meetings);
 - b. paper or "hard copy" (documents, forms, labels, photos); and
 - c. electronic (computer-based records, electronic medical records, scanned documents, video recordings, files on servers and mobile devices, email content and attachments)
- 2. Never knowingly access the records of family members, neighbors, friends, or coworkers without a business need to access the information.
- 3. When disposing of sensitive identifiable data, shred, purge, or totally destroy the media prior to disposal.
- 4. Steps that pharmacy agents can take to secure their environment include:
 - a. always wear an employee identification badge in plain view while at work;
 - b. be aware of which areas are secured (open to authorized staff);
 - c. lock desk, drawer/file cabinet, and workstation when unattended;
 - d. keep desk clear of restricted and sensitive data when not in use;
 - e. clear whiteboards of sensitive information when done or leaving rooms;
 - f. store keys to cabinets, doors, other secure areas in secure locations;
 - g. remember to collect printed documents sent to print at shared network printers;
 - h. arrange workstation monitor so that it is protected from being viewed by unauthorized persons; and
 - i. lock the computer/workstation any time it is not in use.
- 5. Misuse or unauthorized disclosure of sensitive identifiable information may result in penalties. If a pharmacy agent has access to any personally identifiable information or personal health information in any format, the pharmacy agent is responsible for keeping it safe and confidential.

¹² Utah Code 26-61a-501

6. A pharmacy agent must report any actual or suspected failure to protect private information to the facility's pharmacist in charge (PIC).

10. PHARMACY AGENT DUTIES

The following duties may be performed by a pharmacy agent:

- 1. Within the dosage parameters specified by a QMP or PMP, assist the cardholder with understanding available products, proper use of a medical device, medical cannabis strains and methods of consumption or application.
- 2. Using the inventory control system, verify the status of an individual's medical cannabis card and dosage parameters in a patient recommendation.
- 3. Enter and retrieve information from the ICS.
- 4. Authorize entry of a cardholder into the cardholder counseling area.
- 5. Take refill orders from a QMP.
- 6. Provide pricing and product information.
- 7. Accurately process cardholder payments including issuance of receipts, refunds, credits, and cash.
- 8. Prepare labels.
- 9. Retrieve medical cannabis and medical cannabis devices from inventory.
- 10. Accept new medical cannabis or medical cannabis device orders left on voicemail for a PMP to review.
- 11. Verbally offer to a cardholder the opportunity for counseling with a PMP regarding medical cannabis or a medical cannabis device.
- 12. Assist with dispensing of product to cardholders.
- 13. Screen calls for a PMP.
- 14. Preparing inventories of medical cannabis and medical cannabis devices.
- 15. Transport medical cannabis or medical cannabis devices.
- 16. Assist with maintaining a safe, clean, and professional environment.

The following duties <u>cannot</u> be performed by a pharmacy agent:

- 1. Receive dosage parameters for a patient's recommendation over the phone or in person.
- 2. Access patient information in the EVS.
- 3. View medical treatment and medication history in the EVS.
- 4. Determine or modify dosage parameters in a patient's recommendation.
- 5. Provide counseling or consultation regarding a patient's medical condition or medical treatment.¹³

CONTACT INFORMATION

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Updated 05/12/2020

¹³ Utah Admin Code R380-407-2