

## Introduction

Rules referenced: 4-41a-1106(8), R66-5-26, R66-6-7

Per R66, Medical cannabis pharmacy and courier agents are required to complete a one hour continuing education course that has been approved by the Utah Department of Agriculture and Food (UDAF). This course will consist of material regarding Utah medical cannabis law, patient privacy, federal health information privacy laws, and other topics. Pharmacy and courier agents will take this course upon initial registration of their card and for renewals.

The information below is intended to be a guideline for the minimum requirements of information to be included in a pharmacy and courier agent continuing education course. It is a general overview of medical cannabis laws pertaining to medical cannabis pharmacy agents or courier agents in Utah. It only highlights certain sections of federal and state laws, and is not intended to cover all laws applicable to the practice of a pharmacy or courier agent. It also outlines best practices for medical cannabis pharmacy and courier agents.

Applicants for course creation are responsible for reading and understanding all laws pertaining to their registration.

**Utah Medical Cannabis Law** 

## **Utah Medical Cannabis Program Overview**

Proposition 2 was passed in November 2018 and allowed the start of the Utah Medical Cannabis program. The first Medical Cannabis Pharmacies in Utah opened in 2020. All production and pharmacy operations take place within Utah and are overseen by UDAF. Here is a brief summary of the other licence types involved with the program.

#### Production:

- 1. Cultivation there are currently 8 licensees permitted to grow medical cannabis for the program in an indoor or outdoor setting
- 2. Tier 1 Processing allows a facility to process, formulate, package, and label products.

- 3. A Tier 2 Processing allows a facility to package and label products. Testing/Quality Assurance:
  - Laboratory All cannabis products that are sold at a Medical Cannabis Pharmacy must
    pass testing requirements and have a Certificate of Analysis (COA) available. In addition
    to testing for cannabinoids and terpenes, the laboratory will also test for: pesticides,
    heavy metals, solvents, microbial life, toxins, foreign matter, and artificially derived
    cannabinoids

## Medical cannabis card types

Rules referenced: 26B-4-213, 26B-4-214, 26B-4-215, 26B-4-216

Utah residents may apply for medical cannabis cards with a recommending medical provider (RMP) through the Utah electronic verification system (EVS). All card applications for patients who are younger than 21 years must be approved by the Compassionate Use Board.

The types of medical cannabis cards available in Utah and their requirements are listed below.

- Patient card: Issued to patients 21 and older and are valid for one year. Patients that are 18-20 years old require Compassionate Use Board approval.
- <u>Caregiver card:</u> Issued to individuals designated by an active patient cardholder that is unable to go to a medical cannabis pharmacy themselves. Caregiver cards have the same expiration date as the patient's card. Caregivers must complete a fingerprint background check.
- Minor and guardian cards (provisional patient cards): Minor patients are under the age of 18 and require approval from the Compassionate Use Board. A medical cannabis guardian is a parent or legal guardian for the minor patient. Guardians manage their child's medical cannabis account and buy medical cannabis for them. Guardians must complete a fingerprint background check.
- Non-Utah resident card: For out-of-state medical cannabis cardholders visiting Utah.
   These cards are valid for 21 days and are limited to 2 non-resident cards each calendar year. Patients must have a qualifying condition legal in Utah.

# Recommending medical providers

Rules referenced: 26B-4-201(46), 26B-4-204

A recommending medical provider (RMP) is a Utah-licensed physician (MD, DO), advanced practice registered nurse (APRN), physician assistant (PA), or podiatrist (DPM) who recommends medical cannabis for their patients. They can also petition the Compassionate Use

Board (CUB) for patients who are younger than 21 years or who don't have a qualifying condition.

RMPs must complete 4 hours of continuing education specific to medical cannabis every 2 years through formal or informal sources.

RMPs can register in the electronic verification system (EVS) or they can submit a paper medical cannabis certification directly to a medical cannabis pharmacy. They may recommend medical cannabis for up to 1.5% of the total number of Utah medical cannabis patients. Patients don't count towards this limit if an RMP bills insurance for their appointment.

# Qualifying conditions

Rules referenced: 26B-4-203

There are several medical conditions that qualify for a medical cannabis card in Utah. They include:

- acute pain for a condition such as surgery
- Alzheimer's disease
- amyotrophic lateral sclerosis
- autism
- cachexia
- cancer
- Crohn's disease or ulcerative colitis
- epilepsy or seizures
- HIV or AIDS
- multiple sclerosis (MS) or muscle spasms
- nausea that's not caused by pregnancy, cannabis-induced cyclical vomiting syndrome, or cannabinoid hyperemesis syndrome.
- persistent pain that lasts longer than 2 weeks.
- post-traumatic stress disorder (PTSD) that you're also getting treatment for from a mental health provider.
- a rare condition or disease defined by the National Institutes of Health.
- a terminal illness or hospice care with a life expectancy of less than 6 months.

A recommending medical provider can submit a Compassionate Use Board (CUB) petition if someone would like to use medical cannabis as a treatment for another medical condition that's not on this list.

## Dosing guidelines

Ruled referenced: 26B-4-201(22), 26B-4-245

RMPs can recommend specific dosing guidelines (e.g., dosage form, quantity). Pharmacists must ensure patient purchases comply with these guidelines. Pharmacists can make therapeutic substitutions if an RMP authorizes it on the certification. If an RMP provides partial guidelines, pharmacists can determine the remaining aspects through consultation, but cannot change what the RMP has already recommended without approval. If an RMP allows the pharmacist to determine dosing, the pharmacist must consult with the patient, review their medical information, and discuss potential adverse reactions.

## Dosage forms and devices

Rules referenced: 26B-4-201(30), 26B-4-201(38), 4-41a-1102(4)

#### Dosage forms

"Medicinal dosage form" refers to approved forms of processed medical cannabis including: tablets, capsules, concentrated liquids or oils, liquid suspensions that are 30 milliliters or less, topical preparations, transdermal preparations, sublingual preparations (tinctures), gelatinous cubes (gummies) or lozenges, resin or wax, aerosols, suppository preparations, or uniform soft or hard confections that are single servings.

For unprocessed cannabis flower, it refers to a container that has a quantity varying by no more than 10% from the stated weight, is kept in an opaque bag or box when transported or possessed publicly, and is labeled with content, weight, purchase date, legal use termination date, and an inventory control barcode.

"Medicinal dosage form" does not include unprocessed cannabis flower outside its designated container (except for use), unprocessed cannabis flower in a container after its legal use termination date, vaporizing concentrated cannabis with a flame-heated object (like a dab rig), liquid suspensions branded as beverages, substances not measured in grams, milligrams, or milliliters, or substances containing or covered with chocolate

## **Dosage Types**

- No flower = No unprocessed flower.
- No vaping = No vape carts or vape pens.
  - Wax/Resin/Flower is okay
- No Inhalation = no vape carts, vape pens, waxes, resins, other concentrates.

- Flower is okay.
- No edibles = No gummies, lozenges or confections
- No oral preparations = No gummies, lozenges, confections, syringes, oil, liquid suspension, capsules, pills, tinctures, oral spray, aerosols, or edibles
- No topical or transdermal = No balms, bath products, lotions, salves or patches
- No suppositories = No suppositories

#### **Devices**

Medical cannabis device means a device that an individual uses to ingest or inhale medical cannabis.

Medical cannabis device does not include a device that:

- facilitates cannabis combustion; or
- an individual uses to ingest substances other than cannabis.

A medical cannabis pharmacy may not sell medical cannabis in the form of a cigarette or a medical cannabis device that is intentionally designed or constructed to resemble a cigarette.

A medical cannabis pharmacy may sell a medical cannabis device that warms cannabis material into a vapor without the use of a flame and that delivers cannabis to an individual's respiratory system.

## Purchase and possession restrictions

Rules referenced: 26B-4-201(22-23), 26B-4-245, 4-41a-1102

"Legal dosage limit" means an amount that:

- is sufficient to provide 28 days of treatment based on the dosing guidelines that the recommending medical provider or pharmacy medical provider, recommends; and
- may not exceed:
  - 113 grams of unprocessed flower; and
  - o 20 grams of THC in all other products (such as tinctures, vapes, or gummies)

"Legal use termination date" means a date on the label of a container of unprocessed cannabis flower:

• That is 60 days after the date of purchase of the cannabis; after which, the cannabis flower would not be legal outside of the primary residence.

An RMP may petition the Department of Health and Human Services (DHHS) in consultation with the Compassionate Use Board to waive the legal dosage limit if the patient:

- has been diagnosed with a terminal illness:
- has a life expectancy of six months or less; and
- needs the waiver for palliative purposes.

## **Boards**

Rules referenced: 26B-1-435, 4-41a-201.1, R66-9-6

To learn more about the <u>Utah medical cannabis boards</u>, go to the drop down menu under the "Resources" tab. You can also find information on the <u>Utah public notice website</u>.

## Medical Cannabis Policy Advisory Board (MCPAB)

The Medical Cannabis Policy Advisory Board (MCPAB) is a public meeting for anyone involved in Utah's medical cannabis program. They meet monthly to discuss policy issues and then recommend changes to: DHHS, UDAF and State law makers. Some key tasks of the board include:

- Suggesting changes to medical cannabis rules and laws.
- Review new rules related to medical cannabis.
- Advise on issuing new cultivation or pharmacy licenses.
- Consult on patient education and program fees.
- Give input on other medical cannabis issues when asked.
- Review recommendations about potentially harmful substances in medical cannabis products.

## Medical Cannabis Establishment Licensing Advisory Board

The Medical Cannabis Establishment Licensing Advisory Board is a public meeting where all cannabis licensees will present their application renewals and certain change requests. These meetings typically occur 5 times a year. The dates are on the <u>medical cannabis website</u>. Those that are presenting will have a documentation deadline that is typically a month before the meeting itself. These meetings are open to the public, but may enter a closed session depending on subject matter and confidentiality.

#### Compassionate Use Board

The Compassionate Use Board (CUB) includes 7 medical providers from different specialties. Their role is to:

 Review medical cannabis card petitions for patients who don't have a qualifying condition but would still benefit from medical cannabis and patients younger than 21 years. The patient's medical provider submits petitions for review. Coordinate with the Utah Department of Health and Human Services (DHHS) to issue
waivers for medical cannabis patients to purchase more cannabis than the state limit
each month for patients on palliative care. Purchase waivers are for patients who have a
terminal illness, are expected to live for 6 months or less, and who need medical
cannabis for palliative care.

## Agent registration requirements

Rules referenced: 26B-4-219, 4-41a-1106, 4-41a-1107, 4-41a-1204, R66-5-24, R66-5-25, R66-6-5, R66-6-6

#### Pharmacy medical provider

- Pharmacies must employ at least 1 Utah licensed pharmacist who is registered with DHHS as a Pharmacy medical provider (PMP). At least 1 PMP must be onsite at the medical cannabis pharmacy location during public operation hours.
- Ensure the PMP on staff reviews each medical cannabis transaction before dispensing medical cannabis to the cardholder in accordance with pharmacy practice standards.

Each medical cannabis pharmacy will designate 1 PMP as their pharmacist in charge (PIC). A PIC may only act as a PIC for a maximum of 2 locations and is not required to be physically present.

PMP registration expires every 2 years and must be renewed. Registration includes:

- Be at least 21 years of age.
- Complete 4 hours of continuing education approved by DHHS.
- Pay the DHHS application fee.
- Provide the name and location of the pharmacy where they have been offered employment as a PMP.

#### Pharmacy and courier agent

Pharmacy Agent registration is valid for 2 years. Registration requirements for a pharmacy agent include:

- Be at least 21 years of age.
- Complete the continuing education course approved by UDAF and pass the exam.
- Pass a national criminal background check to verify that there are not any state or federal convictions for
  - o a felony within the preceding 10 years;
  - o or after December 3, 2018, misdemeanors for drug distribution.
- Pay the application fee.
- Provide the name and location of the medical cannabis pharmacy where they have been offered employment as a pharmacy agent.

A RMP may not act as a: PMP, PIC, Pharmacy Agent or Courier Agent

# Medical cannabis pharmacy general operating requirements

Rules referenced: 4-41a-1101,R66-5-3, R66-5-4

#### General operating standards

- Pharmacy must be well lit, ventilated, clean and sanitary
- Cannabis must be stored in a secured, designated and clean manner
- Employee list must be maintained by facility and readily available
- Employees must wear an identification tag and carry their UDAF registration card
- Utah medical cannabis law must be available, either in a physical or digital format, that is accessible by all employees
- The medical cannabis pharmacy must prohibit any individual from consuming cannabis products on the property or premises of the pharmacy
- Visitors must be properly documented and escorted
- Advertising parameters
- Targeted marketing parameters
- Business signage/presence
- Posting of purchase limits

#### Compliance with operating plan

- The medical cannabis pharmacy must operate solely at the physical address provided to UDAF and in accordance with the operating plan provided to UDAF.
- Standard operating procedures (SOPs) and state administrative rules and statutes must be available to all pharmacy employees and employees must be familiar with them.
- The medical cannabis pharmacy must notify UDAF before any change in their physical address or operating plan. Changes that have been conditionally approved must be inspected and given final approval before they can be used or implemented in processes.

#### Inventory

- The medical cannabis pharmacy must have an organized inventory.
- Medical cannabis product deliveries must be conducted under the direct supervision of a PMP or a pharmacy agent, who must be present to accept the delivery. After the delivery is complete, the medical cannabis product must immediately be placed in a designated limited-access area.

- A medical cannabis pharmacy must have daily and weekly inventory controls of all medical cannabis products and devices to help the pharmacy detect any diversion, theft, or loss of product in a timely manner.
- If a medical cannabis pharmacy employee identifies an undocumented discrepancy in inventory, the medical cannabis pharmacy needs to determine where the loss occurred, inform UDAF of the loss via telephone, provide a written notice of the loss, and immediately take corrective action within 2 business days of the first discovery of the loss.
- The pharmacist in charge at each medical cannabis pharmacy must conduct an annual inventory audit each year. The annual inventory needs to be signed by the pharmacist who conducted it. Records of annual inventories must be kept for 5 years.

#### Counseling

- A pharmacist must consult with a patient prior to their first medical cannabis purchase.
- The medical cannabis pharmacy must have a designated counseling area to provide confidential patient counseling.
- The medical cannabis pharmacy must provide medical cannabis cardholders a telephone number or website by which the cardholder may contact a pharmacist for counseling.

## Recreational disposition

- No communication or material used in a medical cannabis pharmacy's advertising, educational event, educational material, or targeted marketing may include a recreational disposition.
- A recreational disposition means:
  - An image of a celebrity or other person whose target audience is children or minors.
  - Content that a reasonable person knows or should know appeals to children.
  - Content that encourages, promotes, or otherwise creates the impression that the recreational use of cannabis is legal or acceptable, or that the recreational use of cannabis has potential health or therapeutic benefits.
  - Content that is obscene or indecent.
  - Content that promotes excessive consumption.
  - Slang words or phrases associated with the recreational use of cannabis.
- A medical cannabis pharmacy may reference a cannabis strain name or medicinal dosage form in an educational event, educational material, and targeted marketing even if that name or dosage meets the definition of a recreational disposition.

#### Product waste disposal

- A medical cannabis pharmacy 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.
- A medical cannabis pharmacy shall dispose of any deposited medical cannabis by rendering the product unusable and unrecognizable before transporting it and 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.
  - Other regulations that the department makes in accordance with the Administrative Rulemaking Act.
- A medical cannabis product waste disposal area must be in view of a recording security camera and must be recorded by the security camera.

#### Please check with your designated facility for what their current disposal protocols are

## Medical cannabis pharmacy security operating requirements

- Limited access designation.
- All products that are being disposed of must be clearly marked as, "Not for sale or use."
- A medical cannabis pharmacy must have a single, secure public entrance with a secure lock.
- Every other entrance into the pharmacy and limited access areas where cannabis, cannabis products, and cannabis devices must also be secured with locks. Access to these locked areas, including keys, combination numbers, passcodes, etc., should only be given to authorized personnel.
- A medical cannabis pharmacy may display a sample of each product offered in a securely locked case. This display case must be transparent and not visible from the outside of the pharmacy.
- A medical cannabis pharmacy must have a security system with a back-up power source that detects and records entry into the pharmacy.

# Medical cannabis pharmacy sales

ADD: Rule references: 4-41a-1102(9)

#### Patient sales

 A uniform fee of \$1.50 on each medical cannabis cardholder transaction in a medical cannabis pharmacy must be paid to DHHS.

- Valid patient card and government issued ID must be checked.
- Inventory must update in real time.
- PMP must check each transaction.
- Patient product info insert must be provided with each transaction.
- Provide each cardholder with printed material that includes a pharmacy's contact information and hours when a PMP is available for counseling.

#### **Product labeling**

- Fact/back panel
- Warning labels and disclosures
- Patient and pharmacy labels

#### Delivery services (courier and home delivery)

Rules referenced: 4-41a-102(24), 4-41a-1205(1, 3 & 4), 26B-4-201, 26B-4-214(1)(b)(i), 26B-4-205(4)

A medical cannabis pharmacy may offer home delivery either internally or through a courier service.

Medical cannabis may be delivered to the following locations

- Home address
- Work address as long as it's not a community location
- For a medical cannabis cardholder that is a facility, the facility's address.

#### Vehicle standards

- A list of vehicles used in home delivery must be maintained by the facility and available to UDAF.
- Vehicles must maintain appropriate temperature and storage of the product.
- Must have a GPS device that is not easily removable, is attached to the vehicle, and is capable of storing and transmitting data.
- Is not unmanned.
- No vehicle markings.
- Has an alarm system.
- Make sure that no one other than a pharmacy or courier agent is allowed in the delivery vehicle.

#### Delivery standards

- Record the completion of the shipment by the end of the business day.
- Report missing product to the pharmacy's PMP, UDAF, and law enforcement within 24 hours of noticing that it is missing.

- Return any undeliverable shipment to the pharmacy as soon as possible, but at minimum within 10 business days.
- Have a manifest that includes a unique identifier, origin and destination, departure time, and estimated arrival time.
- Have a trip log showing the specific route.
- Agents must wear an identification tag.
- Drop off delivery only to the cardholder.
- Never consume medical cannabis while delivering.
- Ensure the product is paid for.
- Only transport medical cannabis products or devices that appear on the manifest.
- Deliver products to cardholders between 6 a.m. and 10 p.m.

## Agent duties

Include information from R66-5-23 to educate on Agent duties

# Protection of private information

You must follow state and federal laws about protecting patient information.

- Utah Administrative Rule R383-2-3
- <u>Utah Code 26B-4-2-202(7-9)</u>
- HIPAA laws

Privacy laws state you can only access patient information if you have a legitimate business need for it. Privacy laws also state you should only access the minimum amount of information needed to complete the task.

Utah law states you must safeguard all patient information in the EVS by using these guidelines:

- Do not share patient information with anyone who doesn't have access to the information (such as family, friends, or even other coworkers).
- Do not share patient information with anyone—including coworkers—who don't need to know the information.
- Do not share your login information for the EVS with anyone.

A privacy and security incident is an event that actually or potentially violates privacy and security policies and procedures or compromises information or an information system's confidentiality, integrity, or availability. This can include such things as accidentally losing or releasing information, or misusing information.

Follow these steps if there is a privacy incident or breach, even if it is just for 1 patient.

- 1. Tell your PIC.
- 2. Email the DHHS Center for Medical Cannabis UDAF.

## **Contact information**

Utah Department of Agriculture and Food. Industrial Hemp and Medical Cannabis Division Address: 4315 S 2700 W 2nd Floor, Suite 2200

Taylorsville, UT 84129 Phone: (801) 982-2200 Email: cannabis@utah.gov

Department of Health and Human Services Center for Medical Cannabis

Address: 195 North 1950 West Salt Lake City, Utah 84116 Phone: (801) 538-6504

Email: medicalcannabis@utah.gov