

# Utah Medical Cannabis Act Overview

November 14, 2018

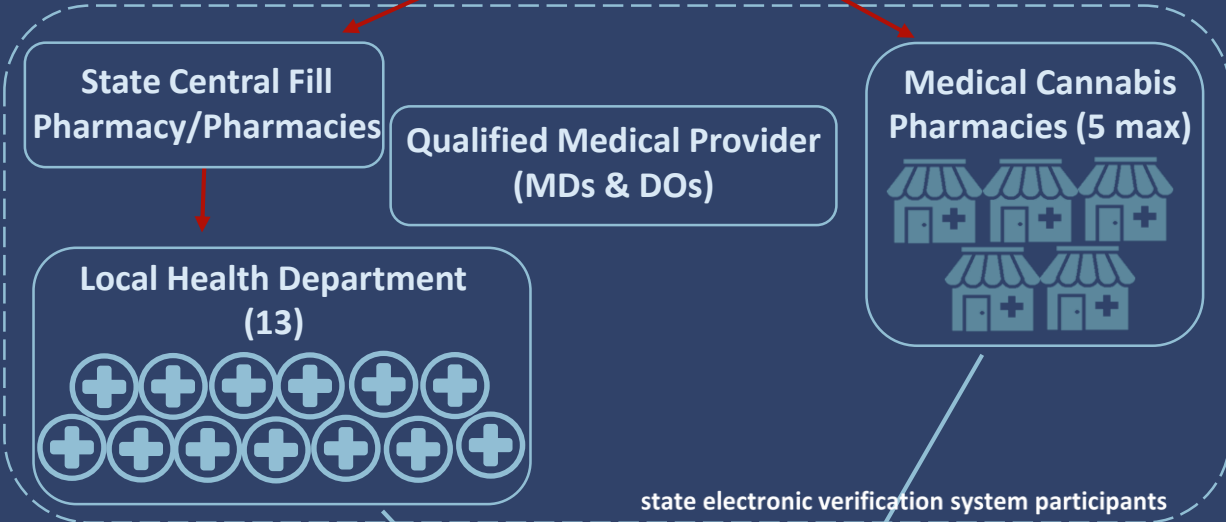
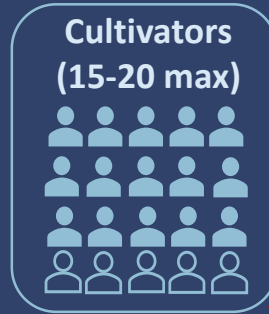


Plant 8" Tall

Inventory Control System

provides for security and tracking of cannabis and a related product from cultivation to patient use.

Patient Use



→ red arrows represent regulated transportation

# Medical Cannabis Card Overview

November 14, 2018

## 1. Doctor Recommendation

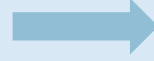


A qualified medical provider (QMP) \*recommends medical cannabis treatment to a patient with a qualifying condition

### Qualifying conditions

- HIV or AIDS
- Alzheimer's disease
- Amyotrophic lateral sclerosis
- Cancer
- Cachexia
- Persistent nausea, under certain conditions
- Crohn's disease or ulcerative colitis
- Epilepsy or debilitating seizures
- Multiple sclerosis or persistent and debilitating muscle spasms
- PTSD, under certain conditions
- Autism
- Terminal illnesses, under certain conditions
- Condition resulting in hospice care
- Rare conditions, under certain conditions
- Pain lasting longer than two weeks, under certain conditions
- Condition the Compassionate Use Board approves, on a case-by-case basis

## 2. Card Application



Patient applies for a medical cannabis card with QMP at QMP's office through Electronic Verification System (EVS)

### Medical Cannabis Patient Card qualifications

- 18 or older
- Utah resident
- Pay fee and cost of criminal background check
- Provide name, gender, age, and address
- Sign acknowledgment of risks
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### Other medical cannabis cards:

- Medical Cannabis Guardian Card
- Provisional Patient Card (for a minor in connection with a Medical Cannabis Guardian Card)
- Medical Cannabis Caregiver Card (for a designated caregiver)

## 3. Card Issuance



The Department of Health evaluates application and issues card within 15 days, if applicant qualifies

### Medical Cannabis Patient Card

- Valid for up to 30 days at first, then 6 months
- Renewable (with fee)

### Medical Cannabis Guardian Card

- Valid for up to 30 days at first, then 6 months
- Renewable (with fee)

### Provisional Patient Card

- Issued automatically with guardian card (no fee)
- Renews automatically with guardian card (no fee)

### Medical Cannabis Caregiver Card

- Generally, card renews automatically with associated medical cannabis patient or guardian card (no fee)

## 4. Cardholder Requirements



Presumption a cardholder possesses cannabis legally, if requirements followed

### A medical cannabis cardholder:

- may only purchase, possess, transport, and (if patient) use certain cannabis in medicinal dosage form
- must carry card on person at all times cardholder is in possession of cannabis
- must have identification label for cannabis in cardholder's possession
- may not use cannabis in public view, except in an emergency
- may not carry on person:
  - more than 113 grams of unprocessed cannabis
  - cannabis product that contains more than 20 grams of THC

*\*QMP's recommendation must be confirmed through either a second opinion or through QMP consultation with another licensed physician*

## Summary of Provisions Governing Cannabis Cultivation Facilities

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- Grows and sells cannabis to another cannabis cultivation facility or to a cannabis processing facility
- License required from Department of Agriculture and Food
  - 15 licenses available in state (up to 20 after 2022 if Department of Agriculture and Food finds there is a public need)
  - Department of Agriculture and Food may revoke license if:
    - the facility is not operating after one year;
    - the facility has been cited for committing three or more of the same type of violation; or
    - the following is convicted of a felony:
      - an individual who has a financial voting interest of 2% or greater in the facility; or
      - an individual who has the power to direct the management or control of the facility
  - License expires every two years
  - Department of Agriculture and Food must begin accepting applications for licensing by Jan 1, 2020
- Subject to Department of Agriculture and Food facility, equipment, compliance, and records inspections at any time during business hours
- Facility must have:
  - a single, secure public entrance
  - a security system with backup power source that:
    - detects and records entry; and
    - provides notice of an unauthorized entry to law enforcement when the facility is closed; and
  - locks on any area where the facility stores cannabis
- Criminal background checks and registration in FBI Rap Back System required for all owners, officers, directors, board members, and employees of the facility
- Must require all employees to register as cannabis cultivation facility agents
- Everyone who works in the facility must be at least 21 and have never been convicted of a felony
- Must operate in a facility that is accessible only to an individual with a valid cannabis cultivation facility agent registration card
- May not advertise to the general public, but may advertise employment opportunities
- Must use inventory control system that:
  - establishes a unique identifier for every plant 8" tall with root ball
  - tracks in real time all cannabis in possession
  - includes a video-recording system that tracks all handling of cannabis and stores video for 45 days; and
  - preserves compatibility with state electronic verification system
- Must render unusable and dispose of any excess medical cannabis material or waste
- May not have any plants visible from perimeter of property
- Must comply with local zoning and permitting requirements
- Must be located in a commercial or industrial zone, and local zoning must allow them in at least one type of both commercial and industrial zoning

## Summary of Provisions Governing Cannabis Processing Facilities

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- Manufactures and sells a cannabis product to the state central fill medical cannabis pharmacy or a medical cannabis pharmacy
- License required from Department of Agriculture and Food
  - Department of Agriculture and Food may revoke license if:
    - the facility is not operating after one year;
    - the facility has been cited for committing three or more of the same type of violation; or
    - the following is convicted of a felony:
      - an individual who has a financial voting interest of 2% or greater in the facility; or
      - an individual who has the power to direct the management or control of the facility
  - License expires every two years
  - Department of Agriculture and Food must begin accepting application by Jan 1, 2020
- Subject to Department of Agriculture and Food facility, equipment, compliance, and records inspections at any time during business hours
- Facility must have:
  - a single, secure public entrance
  - a security system with backup power source that:
    - detects and records entry; and
    - provides notice of an unauthorized entry to law enforcement when the facility is closed; and
  - locks on any area where the facility stores cannabis
- Criminal background checks and registration in FBI Rap Back System required for all owners, officers, directors, board members, and employees of the facility
- Must require all employees to register as cannabis cultivation facility agents
- Everyone who works in the facility must be at least 21 and have never been convicted of a felony
- Must operate in a facility that is accessible only to an individual with a valid cannabis processing facility agent registration card
- May not advertise to the general public, but may advertise employment opportunities
- Must use inventory control system that:
  - establishes a unique identifier for every plant 8” tall with root ball
  - tracks in real time all cannabis in possession
  - includes a video-recording system that tracks all handling of cannabis and stores video for 45 days; and
  - preserves compatibility with state electronic verification system
- May not produce a cannabis product that:
  - the facility knows or should know appeals to children
  - is designed to mimic or could be mistaken for a candy product; and
  - for any flavoring for a product used in vaporization of cannabis or a cannabis product, contains a candy-like flavor or another flavor that the facility knows or should know appeals to children
- For a product that the facility processes or produces, the facility must follow labelling and packaging requirements, including:
  - clearly and unambiguously stating on label that the product contains cannabis
  - placing on the label a unique identification number, connected with the inventory control system, that identifies unique product manufacturing process
  - requirements that the label and package not appeal to children or be similar to a candy container
  - a warning label that states: “WARNING: Cannabis has intoxicating effects and may be addictive. Do not operate a vehicle or machinery under its influence. KEEP OUT OF REACH OF CHILDREN. This product is for medical use only. Use only as directed by a qualified medical provider.”; and
  - for a cube that is designed for ingestion through chewing or holding in the mouth for slow dissolution, the label must also include a warning about the risks of over-consumption
- Must render unusable and dispose of any excess medical cannabis material or waste
- Must be located in a commercial or industrial zone, and local zoning must allow them in at least one type of both commercial and industrial zoning

# Summary of Provisions Governing Independent Cannabis Testing Laboratories

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- Conducts chemical or other analysis of cannabis or a cannabis product
- License required from Department of Agriculture and Food
  - Department of Agriculture and Food may revoke license if:
    - the facility is not operating after one year;
    - the facility has been cited for committing three or more of the same type of violation; or
    - the following is convicted of a felony:
      - an individual who has a financial voting interest of 2% or greater in the facility; or
      - an individual who has the power to direct the management or control of the facility
  - License expires every two years
  - Department of Agriculture and Food will begin accepting application by Jan 1, 2020
  - Department of Agriculture and Food may not issue license to person that:
    - holds a license or has an ownership interest in a medical cannabis pharmacy, a cannabis processing facility, or a cannabis cultivation facility; or
    - has an owner, officer, director, or employee whose family member holds a license or has an ownership interest in a medical cannabis pharmacy, a cannabis processing facility, or a cannabis cultivation facility
- May not be located at same physical location as a medical cannabis pharmacy, a cannabis processing facility, or a cannabis cultivation facility
- Subject to Department of Agriculture and Food facility, equipment, compliance, and records inspections at any time during business hours
- Facility must have:
  - a single, secure public entrance
  - a security system with backup power source that:
    - detects and records entry; and
    - provides notice of an unauthorized entry to law enforcement when the facility is closed; and
  - locks on any area where the facility stores cannabis
- Criminal background checks and registration in FBI Rap Back System required for all owners, officers, directors, board members, and employees of the facility
- Must require all employees to register as cannabis cultivation facility agents
- Everyone who works in the facility must be at least 21 and have never been convicted of a felony
- Must operate in a facility that is accessible only to an individual with a valid independent cannabis testing laboratory agent registration card
- May not advertise to the general public, but may advertise employment opportunities
- Must use inventory control system that:
  - establishes a unique identifier for every plant 8” tall with root ball
  - tracks in real time all cannabis in possession
  - includes a video-recording system that tracks all handling of cannabis and stores video for 45 days; and
  - preserves compatibility with state electronic verification system
- Must render unusable and dispose of any excess medical cannabis material or waste
- Tests a representative sample of cannabis or cannabis product to determine:
  - the amount of THC and CBD and whether it matches the label
  - the amount of any other cannabinoid in the cannabis or cannabis product the label claims the cannabis or cannabis product contains
  - that the presence of contaminants does not exceed an amount that is safe for human consumption; and
  - that a cannabis product does not contain a level of residual solvent that is not safe for human consumption
- Department of Agriculture and Food may establish standards, methods, practices, and procedures for testing cannabis and cannabis products.
- Reports to the Department of Agriculture and Food any cannabis or cannabis product that it determines is unsafe for human consumption

## Summary of Provisions Governing Medical Cannabis Pharmacies

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- Sells cannabis in a medicinal dosage form, cannabis product in a medicinal dosage form, and medical cannabis devices to medical cannabis cardholders
- License required from Department of Health
  - Five licenses available in state (may increase incrementally to 10 if the state central fill medical cannabis pharmacy does not meet certain operational deadlines)
  - Department of Agriculture and Food may revoke a license if the pharmacy is not operating after one year, if the pharmacy has been cited for committing three or more of the same type of violation, or if the owner/operator is convicted of a felony
  - License expires every two years
  - Department of Health must begin accepting application by March 1, 2020
- Must maintain inventory control system
- Must use state electronic verification system and preserve compatibility with inventory control system
  - Must submit record to state electronic verification system each time the pharmacy dispenses cannabis or a cannabis product to individual with a medical cannabis card
- May only sell:
  - cannabis in a medicinal dosage form
  - cannabis product in a medicinal dosage form
  - a medical cannabis device; and
  - educational material related to medical use of cannabis
- An individual must be at least 18 to enter
- Criminal background checks and FBI Rap Back System registration required for each individual who has a financial or voting interest of 2% or greater in the pharmacy or has power to direct or cause the management or control of the pharmacy
- Must require all employees to register as medical cannabis pharmacy agents
- Pharmacy must have:
  - a single, secure public entrance
  - a security system with backup power source that:
    - detects and records entry; and
    - provides notice of an unauthorized entry to law enforcement when the pharmacy is closed; and
  - locks on any area where the pharmacy stores cannabis
- Must post limits on purchases
- May not sell a cannabis-based drug that the United States Food and Drug Administration has approved
- May not sell to a cardholder in any 12-day period more than the lesser of:
  - an amount sufficient to provide 14 days of treatment based on the dosing parameters that the relevant qualified medical provider recommends; or
  - 56 grams of unprocessed cannabis or an amount that contains more than 10 grams of THC
- Required to employ and register with the Department of Health a pharmacy medical provider, including a pharmacist-in-charge (and have at least one pharmacist onsite during business hours to consult with patients)
  - pharmacy medical providers must complete certain continuing education requirements
- May not allow an individual to use cannabis on premises
- May not give samples
- Must put the name of pharmacy on cannabis or cannabis product sold
- May only sell to someone with a medical cannabis card and corresponding photo ID
- May not advertise in any medium
- May have signage that may include a green cross, the name of pharmacy, and the hours of operation
- Must follow specific labeling requirements for all cannabis and cannabis product sold
- Must be located in area where zoning allows for a business that sells alcohol or a retail tobacco specialty business
- May, under certain conditions, create a medical cannabis disposal program that allows individuals to deposit unused or excess medical cannabis, cannabis residue from a medical cannabis device, or medical cannabis products in a locked box or other secure receptacle within the pharmacy.

# Summary of Provisions Governing State Central Fill Medical Cannabis Pharmacy

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- Department of Health must establish, or contract to establish, a State Central Fill Medical Cannabis Pharmacy before July 1, 2020
- May be at more than one location, if analysis determines necessary
- Procures cannabis that a cannabis processing facility processes into a medicinal dosage form
- Receives requests for shipments from patients with verification through the state electronic verification system or from medical providers directly through the state electronic verification system
- May only prepare, ship, or sell the following items:
  - cannabis in a medicinal dosage form
  - cannabis product in a medicinal dosage form
  - a medical cannabis device; and
  - educational material related to medical use of cannabis
- Prepares shipments and records information in the state electronic verification system
- May communicate and consult directly with the patient when the qualified medical professional recommending a medical cannabis treatment does not provide dosing parameters
- Processes payment electronically
- Delivers patient orders to the patient's corresponding local health department for distribution to the patient—must be delivered within two business days of receiving the shipment request
  - Local health department designates distribution agents to handle central fill shipments
  - Local health department distribution agents verify information regarding state central fill shipments and ensure that patients picking up the state central fill shipments have a medical cannabis card with corresponding photo identification
- May not prepare a state central fill shipment in any 12-day period for more than the lesser of:
  - an amount sufficient to provide 14 days of treatment based on the dosing parameters that the relevant qualified medical provider recommends; or
  - 56 grams of unprocessed cannabis or an amount that contains more than 10 grams of THC
- May not sell a cannabis-based drug that the United States Food and Drug Administration has approved
- Required to employ and register with the Department of Health a state central fill pharmacy medical provider, including a pharmacist-in-charge (and have at least one pharmacist onsite during business hours to consult with patients)
  - State central fill pharmacy medical providers must complete certain continuing education requirements
- Must include in each shipment written counseling regarding the shipment and provide a telephone number or website by which a cardholder may contact a pharmacy medical provider for counseling
- Must complete background check for and register in the FBI Rap back System each state central fill agent
- May not advertise in any medium
  - May maintain a website to provide information regarding the central fill process
- Must follow specific labeling requirements for all cannabis and cannabis product sold, including:
  - the name and phone number of the central fill medical cannabis pharmacy
  - an assigned serial number
  - the date of sale
  - the name of the medical cannabis cardholder to whom it was sold
  - the name of the qualified medical provider who recommended medical cannabis treatment
  - the amount dispensed and the cannabinoid content; and
  - the beyond use date

## Summary of Provisions Governing Qualified Medical Providers

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- Must register with the Department of Health in order to recommend medical cannabis treatment to a patient
  - registration expires every two years but is renewable
- Registration requires that the individual:
  - be licensed, in good standing, as an MD or DO
  - be licensed to prescribe a controlled substance; and
  - possess the authority, in accordance with scope of practice, to prescribe a Schedule II controlled substance
- Must complete 4 hours of continuing education regarding the medical use of cannabis:
  - before registering with the Department of Health; and
  - each continuing education cycle
- May not recommend medical cannabis treatment to a more than 175 of patients at any given time, unless certified in certain specialties (in which case, may recommend medical cannabis treatment to up to 300 of patients at any given time)
- May petition Division of Occupational and Professional Licensing for authorization to exceed the 175- or 300-patient limit by up to 100 patients
- May only recommend the medical cannabis treatment to a patient in the course of physician-patient relationship after completing and documenting in patient's record a thorough assessment of patient's condition and medical history
- May not receive any compensation or benefit from a cannabis cultivation facility, a cannabis processing facility, a medical cannabis pharmacy, or the state central fill medical cannabis pharmacy for recommending medical cannabis treatment for a patient
- May not advertise that the qualified medical provider recommends medical cannabis treatment
- May, through a website, post:
  - a green cross
  - any qualifying condition that the qualified medical provider treats
  - any scientific study regarding medical cannabis treatment
- Under specific conditions, is not subject to the following:
  - civil or criminal liability; or
  - licensure sanctions
- Must use reasonable and ordinary care in the treatment of a patient



## Summary of Provisions Governing the Medical Cannabis Inventory Control System

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- Tracks cannabis using a unique identifier, in real time, once the cannabis plant is 8 inches tall and has a root ball until the cannabis or cannabis product is disposed of or sold to a medical cannabis cardholder
- Must be used by:
  - cannabis cultivation facilities
  - cannabis processing facilities
  - independent cannabis testing laboratories
  - medical cannabis pharmacies; and
  - the state central fill medical cannabis pharmacy
- Stores, in real time, a record of the amount of cannabis and cannabis product in the possession of an entity that uses the system
- Includes a video-recording system that:
  - tracks all handling and processing of the cannabis
  - is tamper proof; and
  - stores a video record for 45 days
- Preserves compatibility with the state electronic verification system
- Each entity that uses the system must permit the Department of Health to access the system at any time

## Summary of Provisions Governing the Transportation of Medical Cannabis

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- Except for an individual with a valid medical cannabis card, an individual may not transport cannabis in a medicinal dosage form, a cannabis product in a medicinal dosage form, or a medical cannabis device unless the individual:
  - is a registered agent of:
    - a cannabis cultivation facility
    - a cannabis processing facility
    - an independent cannabis testing laboratory
    - a medical cannabis pharmacy; or
    - the state central fill medical cannabis pharmacy
  - OR
  - is a courier for the state central fill medical cannabis pharmacy
- Only an agent of a cannabis cultivating facility, when transporting cannabis plants to a cannabis processing facility or an independent cannabis testing laboratory, may transport unprocessed cannabis outside of a medicinal dosage form
- An individual transporting cannabis, a cannabis product, or a cannabis medical device (unless the individual has a valid medical cannabis card) must possess a transportation manifest that:
  - includes a unique identifier link from the cannabis, cannabis product, or cannabis medical device to the inventory control system
  - includes the origin and destination of the cannabis, cannabis product, or cannabis medical device
  - indicates the departure and arrival times and locations of the individual transporting the cannabis, cannabis product, or cannabis medical device
- An individual who does not follow these requirements is guilty of an infraction and subject to a \$100 fine

## Summary of Provisions Governing the Electronic Verification System

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- Must be established on or before March 1, 2020
- Allows an individual to apply for a medical cannabis patient card or, if applicable, a medical cannabis card:
  - with the individual's qualified medical provider; and
  - in the qualified medical provider's office
- allows an individual to apply to renew a medical cannabis patient card or a medical cannabis guardian card under certain conditions
- allows a qualified medical provider to:
  - access dispensing and card-status information regarding a patient;
  - electronically recommend treatment with cannabis and dosing parameters;
  - electronically renew a recommendation; and
  - at the request of the medical cannabis cardholder, initial a state central fill shipment
- connects with an inventory control system that a medical cannabis pharmacy and the state central fill medical cannabis pharmacy use to track and archive purchases of cannabis, cannabis product, or a cannabis device
- Provides access to the Department of Health, the Department of Agriculture and Food, and the Division of Occupational and Professional Licensing to the extent necessary to carry out functions and responsibilities
- Provides access to and interaction with the state central fill medical cannabis pharmacy, state central fill agents, and local health department distribution agents, to facilitate the state central fill shipment process
- Provides access to state or local law enforcement under certain conditions