

Released: October 13, 2023

To: Medical Cannabis Policy Advisory Board (MCPAB)
From: Sara Lealos, Operations Team Manager, Utah Department of Health and Human Services (DHHS), Center for Medical Cannabis
Subject: **DHHS Center for Medical Cannabis (CMC) rule change filing**

Introduction

The DHHS Center for Medical Cannabis is requesting the Medical Cannabis Policy Advisory Board review proposed rule changes that will be filed in November 2023.

Background

The DHHS Center for Medical Cannabis rules are being updated to match new laws that changed which department regulates medical cannabis pharmacies. Other changes are made to help DHHS manage the Utah medical cannabis program.

Next steps

DHHS will submit rule changes to the Office of Administrative Rules (OAR). The Office of Administrative Rules will include the rule changes in the public bulletin released on November 15, 2023. A public rule hearing will be scheduled for November 28, 2023. If there are no public comments or if the public comments can be addressed without rewriting the rules, the changes will go into effect January 1, 2024.

Rule change descriptions

This section includes a summary for each rule change being filed. To review the specific language for each rule change filing, read through the rule change section below.

Repealed rules

The following rules will be repealed by DHHS and reinstated by UDAF:

- DHHS R383-7 Medical Cannabis Pharmacy will become part of UDAF admin. rule R68.
- DHHS R383-8 Medical Cannabis Pharmacy Agent will become part of UDAF admin. rule R68.
- DHHS R383-9 Home Delivery and Courier will become part of UDAF admin. rule R68.
- DHHS R383-14 Administrative Penalties - already part of UDAF admin. rule R68.

Amended rules

The following DHHS rules will be amended:

- R383-1 Definitions
 - Removes terms that will be incorporated into UDAF admin rules.
 - Adds a definition of QMP proxy.
- R383-2 Electronic Verification System and Inventory Control System.
 - Adds QMP proxies as medical cannabis staff members who can access patient records in EVS.
 - Removes courier agents and production establishment agents as medical cannabis staff members who can access patient records in EVS.

- Adds a section that requires EVS users to safeguard their login information.
- R383-4 Qualified Medical Providers
 - Provides instructions to QMP proxies about applying and renewing their EVS registration.
- R383-5 Dosing Guidelines
 - Moves partial fill requirements from DHHS rule R383-7 to R383-5. The actual language will stay the same in the new rule.

Rule changes

R383-1. Definitions.

R383-1-1. Authority and Purpose.

Pursuant to Subsection 26B-1-202(1), this rule defines terms used in Title R383.

R383-1-2. Definitions.

(1) The definitions in Section 26B-4-201 apply to this rule. In addition, the following applies to this rule.

~~[(2) "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.]~~

~~[(3)](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.~~

~~[(4) "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.]~~

~~[(5) "Courier agent" means a medical cannabis courier agent.]~~

BOARD AGENDA:
ITEM:

[(6)](3) "Department" 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 [actual] educational event; or

— (b) any printed educational material such as a placard, poster, fact sheet, book, pamphlet, flyer, or business card.]

[(10)](4) "EVS" means the electronic verification system.

[(11)](5) "Fundamentals of medical cannabis coursework" means a course, or combination of courses, with content that addresses the following subjects:

(a) the endocannabinoid system and phytocannabinoids;

(b) general guidance and recommendations for medical cannabis; and

(c) history of cannabis, dosing forms, considerations, drug interactions, adverse reactions, contraindications, such as breastfeeding and pregnancy, and toxicology.

[(12)](6) "General medical cannabis coursework" means a course or combination of courses with content that addresses medical cannabis, which may include medical cannabis law or fundamentals of medical cannabis coursework.

BOARD AGENDA:
ITEM:

[(13)](7) "ICS" means the inventory control system.

[(14)](8) "Institutional review board" or "IRB" means the same term as defined in Section 26B-4-[201]212(1)(f).

[(15)](9) "Law enforcement personnel" means law enforcement personnel with access to UC[+]JIS.

[(16)] "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.

— (17) "LMP" means a limited medical provider.]

[(18)](10) "Mail" means to send through mail services, email, or hand-delivery.

[(19)](11) "Medical cannabis law coursework" means a course, or combination of courses, with content that addresses Title 26B, Chapter 4, Part 2 Cannabinoid Research and Medical Cannabis and other state and federal laws relating to medical cannabis; that includes, at a minimum, a review of the following:

(a) qualifying health conditions for which a patient may lawfully use medical cannabis for medicinal purposes in Utah;

(b) forms of medical cannabis that qualifying patients are allowed and prohibited under Utah law;

(c) limits of the quantities of unprocessed cannabis and cannabis products in a medicinal form that may be dispensed in Utah;

(d) requirements to initially register, and renew a registration, as a QMP;

BOARD AGENDA:
ITEM:

- (e) limits to the number of active medical cannabis recommendations that an RMP can make at any given time;
- (f) description of what an RMP must document in a patient's record before recommending medical cannabis;
- (g) information required from an RMP when writing a medical cannabis recommendation, and the option to make a recommendation without specifying a dosage form and dosing guidelines;
- (h) a PMP's role in determining the appropriate medical cannabis dosage form and dosing guidelines when an RMP chooses to recommend without specifying a dosage form and dosing guidelines;
- (i) limits on advertising by an RMP;
- (j) types of medical cannabis cards;
- (k) regulations controlling the distribution of products by medical cannabis pharmacies;
- (l) partial fill orders;
- (m) the role of the Compassionate Use Board;
- (n) that all medical cannabis purchased at medical cannabis pharmacies in Utah shall be cultivated at cannabis cultivation facilities, processed at cannabis processing facilities, and that samples be tested at independent cannabis testing laboratories; that is licensed in Utah and operate within Utah's medical cannabis system;
- (o) the conditions of legal possession of medical cannabis under Utah law;
- (p) the legal status of medical and recreational marijuana in states surrounding Utah and under federal law;
- (q) authority to change dosage parameters in a medical cannabis recommendation;
- (r) home delivery of medical cannabis; and

BOARD AGENDA:
ITEM:

(s) purpose of the state central patient portal.

[(20)](12) "Pharmacy agent" means a medical cannabis pharmacy agent.

[(21) "PIC" means a pharmacist in charge who oversees the operation and generally supervises a medical cannabis pharmacy.]

[(22)](13) "PMP" means a medical cannabis pharmacy medical provider.

[(23) "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 of the medical cannabis pharmacy.]

[(24)](14) "QMP" means a qualified medical provider.

[(25) "Recreational disposition" means the following:

____ (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.]

(15) "QMP Proxy" or "Qualified Medical Provider Proxy" means an individual that has been given authority to enter certifications and recommendations for a QMP as described in 26B-4-202(3).

[(26)](16) "RMP" [-]means a recommending medical provider.

BOARD AGENDA:
ITEM:

[(27)](17) "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.

[(28)](18) "State agency employee" means an employee of the Utah Department of Health and Human Services, Utah Department of Agriculture and Food, Division of Technology Services, and the Utah Department of Commerce, Division of Professional Licensing.

[(29)](19) "Substantial evidence" or "substantial clinical data" means evidence that two or more clinical studies support. The clinical studies shall meet the following criteria:

- (a) were conducted under a study approved by an IRB;
- (b) were conducted or approved by the federal government;
- (c) are cited by the Department in educational materials posted on its website; or
- (d) are of reasonable scientific rigor as determined by the Department.

[(30)](20) "UC[H]IS" means the Utah Criminal Justice Information System.

[(31)](21) "UDAF" means the Utah Department of Agriculture and Food.

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

R383-2. Electronic Verification System and Inventory Control System.

R383-2-1. Authority and Purpose.

- (1) Subsections 26B-1-202(1) and 26B-4-202(6) authorize this rule.

BOARD AGENDA:
ITEM:

(2) This rule establishes EVS and ICS access limitations and standards and confidentiality requirements.

R383-2-2. Access Limitations and Standards.

(1) An individual shall request access to the data in the EVS and ICS by creating an account to begin an EVS or ICS application process.

(2) The following individual may access information in the EVS about themselves, or another cardholder for whom they are a guardian or caregiver, to the extent allowed in Title 26B, Chapter 4, Part 2, Cannabinoid Research and Medical Cannabis or Title 4, Chapter 41a, Cannabis Production Establishments and Pharmacies Utah Cannabis Production Establishments:

- (a) a medical cannabis patient cardholder;
- (b) a medical cannabis guardian cardholder; and
- (c) a medical cannabis caregiver cardholder.

(3) The Department shall grant EVS access to the extent allowed in Title 26B, Chapter 4, Part 2, Cannabinoid Research and Medical Cannabis or Title 4, Chapter 41a, Cannabis Production Establishments and Pharmacies Utah Cannabis Production Establishments, and this rule to the following individuals:

- (a) a QMP;
- (b) a PMP;
- (c) a QMP Proxy;
- ~~(d) a pharmacy agent;[~~
- ~~(d) a courier agent;~~
- ~~(e) a cannabis production establishment agent;]~~
- ~~(f) a state agency employee; or~~
- ~~(g) law enforcement personnel.~~

BOARD AGENDA:
ITEM:

(4) The type of EVS and ICS access granted by the Department shall depend on the type of card or license issued.

R383-2-3. Confidentiality Requirements.

(1) A person authorized to access information in the EVS and the ICS shall access only the minimum amount of information necessary to perform an authorized function specified in Chapter 26B, Chapter 4, Part 2 Cannabinoid Research and Medical Cannabis or Title 4, Chapter 41a, Cannabis Production Establishments and Pharmacies ~~Utah Cannabis Production Establishments~~, Rule R68-27, Cannabis Cultivation, and this rule.

(2) A person authorized to access information in the EVS and the ICS shall safeguard all information stored in those systems, including specific information about medical cannabis cardholders.

(3) A person authorized to access information in the EVS and the ICS shall safeguard their login credentials and not share them with anyone.

[(3)](4) A person authorized to access the EVS or ICS who fails to observe the confidentiality requirement of this rule may lose access to the EVS and ICS and may be subject to the penalties provided in Section 26B-4-202.

R383-4. Qualified Medical Providers and Qualified Medical Provider Proxies.

R383-4-1. Authority and Purpose.

(1) Subsection 26B-1-202(1) authorizes this rule.

(2) This rule establishes application procedures for QMPs and QMP Proxies, as well as continuing education requirements for QMPs.

R383-4-2. Application Procedures.

BOARD AGENDA:
ITEM:

(1) The application procedures established in this section shall govern the application for the initial issuance of a QMP or QMP Proxy registration card under Title 26B, Chapter 4, Part 2, Cannabinoid Research and Medical Cannabis.

(2) Each applicant shall apply upon forms available in the EVS, from the Department.

(3) The Department may issue a QMP or QMP Proxy registration card, only if the Department determines that the applicant meets all requirements established under Title 26B, Chapter 4, Part 2, Cannabinoid Research and Medical Cannabis, and by Department rule.

(4) The Department shall provide written notice of denial to an applicant who submits an incomplete application or if the Department determines that the applicant does not meet the requirements.

(5)(a) The Department shall provide to the applicant a written notice of an incomplete application and that the application is denied.

(b) The Department shall not accept the application unless the applicant corrects the deficiencies within the time period specified in the notice and otherwise meets all requirements.

(6) The Department shall provide written notices of denial or incomplete application to the applicant's last email address shown in the Department's EVS database unless the applicant has requested to be notified by regular mail.

(7)(a) Each applicant shall maintain a current email address with the Department.

(b) Notice to the last email address on file with the Department constitutes legal notice unless the applicant has requested to be notified by regular mail.

R383-4-3. Renewal Application Procedures.

(1) Renewal application procedures established in this section shall govern applications to renew a QMP or QMP Proxy registration card.

BOARD AGENDA:
ITEM:

(2) Each QMP or QMP Proxy registration card applicant shall apply upon renewal application forms, available from the Department.

(3) The Department may issue a QMP or QMP Proxy registration card to an applicant who submits a complete renewal application, and the Department determines that the applicant meets the requirements.

(4) The Department shall provide written notice of denial to the applicant who submits an incomplete renewal application or if the Department determines that the applicant does not meet the requirements.

(5) The Department shall provide the applicant a written notice of an incomplete application and that the renewal application will be denied, unless the applicant corrects the deficiencies within the time period specified in the notice, and otherwise meets all requirements.

(6)(a) The Department shall send a renewal notice to each cardholder at least 30 days before the expiration date shown on the QMP's or QMP Proxy's card.

(b) The notice shall include instructions on how to renew their QMP or QMP Proxy registration card in the EVS, via the Department's website.

(7) The Department shall send renewal notices to the cardholder's last email shown in the Department's EVS database unless the applicant has requested to be notified by regular mail.

(8)(a) Each cardholder shall maintain a current email address and mailing address with the Department.

(b) Emailing to the last email address on file with the Department constitutes legal notice unless the applicant requests to be notified by regular mail.

(9) Renewal notices shall advise each cardholder that a QMP or QMP Proxy registration card automatically expires on the expiration date, and is no longer valid.

(10) If an individual's QMP or QMP Proxy registration card expires, the individual may submit a QMP registration card renewal application at any time, regardless of the length of time passed since the expiration of the card.

BOARD AGENDA:
ITEM:

R383-4-4. Continuing Education Requirement.

- (1)(a) Applicants registering for a QMP registration card shall verify the completion of four hours of continuing education.
- (b) Once registered as a QMP, an individual shall complete an additional four hours of continuing education every two years.
- (2) Requirements for renewal shall include:
 - (a) completion of continuing education coursework that shall:
 - (i) be approved by the Department; or
 - (ii) be provided by organizations accredited through the Accreditation Council for Continuing Medical Education, Accreditation Council for Pharmacy Education, American Academy of Physician Assistants, or the American Association of Nurse Practitioners;
 - (b) a completion test with a passing score, as determined by the course provider, to verify comprehension of course content; and
 - (c) a certificate of completion.
- (3) Initial registration as a QMP, requires at least four hours of continuing education, which shall include at a minimum:
 - (a) medical cannabis law coursework; and
 - (b) fundamentals of medical cannabis coursework.
- (4) A QMP shall renew registration every two years, after completing at least four hours of continuing education in:
 - (a) medical cannabis law coursework; and
 - (b) general medical cannabis coursework.
- (5)(a) The QMP shall submit their continuing education report along with their application for registration as a QMP, and shall include a certificate of