MINUTES FROM NDP MAS NURSE/MATT RN QUARTERLY MEETING Thursday, May 16, 2024

Beverly Jackson, NDP Coordinator, conducted Roll Call for MATT RNs. All MAS Nurses were instructed to document names in Chat Box as proof of attendance.

Per Beverly Jackson:

- What's Happening in Pharmacy:
 - AL Medicaid Agency Alert dated March 4, 2024 talks about Opioid Cumulative Daily Morphine Milligram Equivalents (MME) Limits – MME Decrease; effective April 1, 2024. (See attachment.)
 - Recall of Equate Lubricant Eye Ointment, Equate Stye Lubricant Eye Ointment, CVS Health Lubricant Eye Ointment, and Lubricant PM Ointment by Brassica Pharma due to lack of sterility. (See attachment.)
 - AL Medicaid Cannabis Commission Administrative Code Chapter 538-X-2:
 Regulation of Patients and Caregivers.
 - > No one in the population we served is using Cannabis to her knowledge
 - Not approved to be used in ADMH CRFs to her knowledge

Changes in MAC I Modules Revisions:

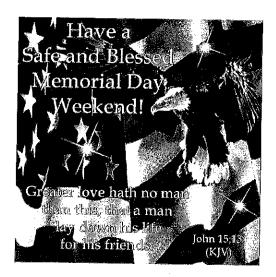
- 5 attempts to pass each module remains. No reset; recommending allowing potential candidates to retake after 6 months. Still awaiting approval.
- NDP Advisory Committee reviewed all 6 modules and addressed each question with a passing rate of less than 70%.
 - Revisions were made to approximately 6 questions to make them more clear and concise.
 - One question was confusing and had to be removed.
 - One question was clear and was let alone. The goal is for MAC Candidate to learn and comprehend.
 - Still awaiting approval from the ABN regarding the revised MAC I Modules; the old modules are still on the Relias Website.
- At present, MAC Workers <u>can not</u> crush medications; a procedure to allow MAC Workers to crush medications has been added to the revised MAC I Module – 6; still awaiting approval from the ABN.
- If Ms. Jackson hasn't heard from the ABN by the end of month, she will contact them again related to approval of MAC I Modules Revisions.

- A Fall Assessment template was reviewed during the meeting.
 - Plan is to add it to the Comprehensive Nursing Assessment on the NDP Website if approved
 - > If your agency has a current Fall Assessment, you can continue to use it.
 - > It was reported there are changes in IPMS related to reportable falls.
 - > There is in increase in falls; Certification Surveyors stated staff are not being trained properly on usage of medical equipment to prevent falls.
- An AIMS Assessment template was reviewed as well.
 - MAS Nurse or Physician can complete the form.
 - > If your agency has an AIMS Assessment, you can continue to use it.
 - > AIMS Assessments are completed for psychotropic medications as well as for other medications that may cause involuntary movement (i.e. Reglan).
- ADMH Statewide IRC Quarterly Data was reviewed. (See Agenda related to Medication Errors.)
 - Some of the data related Medication Errors appears inaccurate; refusals are being counted under Omissions which is not correct. The person did not miss the dose, it was refused which is clinical issue.
 - > MAS Nurses were instructed to stress to MAC Workers the importance of administering the correct medications to the correct Persons to keep them safe.
 - The majority voted to keep reviewing IRC Quarterly Data during the MAS/MATT meetings.
- <u>Dates for upcoming NDP Training</u> (Becoming an Approved Delegating Nurse and MAS Nurse Update 2024) taught by Beverly Jackson, NDP Coordinator, are listed on the attached Agenda.
 - Must register on the following website:
 www.admh.academy.reliaslearning.com
 - Training is conducted via Zoom
 - Some MATT RNs conduct NDP Training as well that is not listed on the Relias Website or the Agenda.
- Next MATT RN Training will be on July 30th and July 31st. There are currently 4 applicants.

- Next Meeting Date: Thursday, August 15, 2024
 - Send an email to Beverly Jackson, NDP Coordinator, if you would like to receive invites to MAS/MATT Meetings if not already receiving them.
 - Remaining Meeting Dates for 2024
 - a. August 15, 2024
 - b. November 21, 2024

Attachments:

- Meeting Agenda
- Draft of Fall Assessment
- Draft of AIMS Assessment
- Alabama Medicaid Agency Alert
- Recall of Equate Lubricant Eye Ointment, Equate Stye Lubricant Eye Ointment, CVS Health Lubricant Eye Ointment, and Lubricant PM Ointment by Brassica Pharma due to lack of sterility
- AL Medicaid Cannabis Commission Administrative Code Chapter 538-X-2:
 Regulation of Patients and Caregivers



Submitted By:

Angela W. Marks, RNIII N Regional Nurse, ADMH – Region 3

Date: May 23, 2024

MAS/MATT MEETING AGENDA May 16, 2024 10a-12noon zoom

- Welcome EVERYONE <u>sign in by entering your name in the chat box</u>.
 This will serve as our roster.
 - MATT nurse Roll call
 - What's Happening in Pharmacy
 - a. Medicaid Alert March 7, 2024

RE: Opioid Cumulative Daily Morphine Milligram Equivalents (MME) Limit – MME Decrease See attach Pharmacy News - information on Medicaid Alert

- MAC | Revisions
 - 5 attempts for each Module no reset
 Executive Advisory Committee Review Relias analysis reports on MAC exams. !6 questions were identified with a passing rate less than 70%. Committee reviewed and modified 14 questions, removed one all together and left one alone.
 - Still awaiting the ABN approval on the revised MAC I modules
 - crush meds procedure via pouches/envelops added to module 6
 - Falls assessment Aims Assessment
- ABN updated their website Mandatory CEs also update February 2024
- ADMH STATEWIDE IRC Data

Med errors

- o Level II for January -March
- o 4 level !! Three were wrong person errors One Missed dose
- 0 Level IIIs
- o Missed doses 483 an increase from last qtr 462
- o Wrong med-10 down by 2
- o Wrong dose -58 down from 68
- Other business
 - Medical marijuana

2024 training dates on Relias.

b. Becoming a Certified Delegating Nurse (Initial Training)

- i. June 11 & 12
- ii. July 9 & 10
- iii. August 13 & 14
- iv. September 10 & 11
- v. October 8 & 9
- vi. November 12 & 13
- vii. December 10 & 11

c. MAS UPDATE 2024

- i. May 22
- ii. June 19
- iii. July 17
- iv. August 21
- v. September 18
- vi. October 16
- vii. November 20
- viii. December 18

Next MAS/MATT Training

- a. 4 applicants- Training set for : July 30 & 31
- Next MAS/Matt Meetings
 - a. August 15
 - b. November 21
- How do I register for training?

www.admh.academy.reliaslearning.com

If you have a problem with Relias, I cannot fix it you must call them.1.800.381.2321 **FYI-** my vacation time - September 23-27

Nurse Delegation Program Fall Scale

The items in the scale are scored as follows:

History of falling: This is scored as 5 if the person has fallen during the 3 months prior to admission or within the last 3 months at your facility or if there was an immediate history of physiological falls, such as from seizures or an impaired gait.

If the person has not fallen, this is scored $\underline{0}$. Note: If a person falls for the first time, then his or her score immediately increases by $\underline{5}$.

Secondary diagnosis: This is scored as $\underline{\mathbf{5}}$ if $\underline{\mathbf{more\ than\ one\ medical\ diagnosis}}$ is listed on the person's chart; if not, score $\underline{\mathbf{0}}$. (Example: Cerebral Palsy and Epilepsy)

Ambulatory aids: This is scored as $\underline{0}$ if the person does not use any assistive devices. If they walk with a walking aid, use a wheelchair, crutches or hold onto the furniture, are on a bed rest this is a score of $\underline{10}$. (Note: only *one score* even if multiple devices)

Two or More sedation meds: This is scored as $\underline{5}$ if the person has two or more medications that cause sedation; if not, score $\underline{0}$.

Gait: A normal gait is characterized by the person walking with head erect, arms swinging freely at the side, and striding without hesitant. This gait scores $\underline{0}$.

With a weak gait (score as 5), the person is stooped but can lift the head while walking without losing balance. Steps are short and the person may shuffle.

With an impaired gait (score 10), the person may have difficulty rising from the chair, attempting to get up by pushing on the arms of the chair/or by bouncing (i.e., by using several attempts to rise). The person's head is down, and he or she watches the ground. Because the person's balance is poor, the person grasps onto the furniture, they require a support person, or a walking aid for support and cannot walk without this assistance.

Mental status: When using this Scale, mental status is measured by checking the person's own self-assessment of his or her own ability to ambulate. Ask the person (when applicable), "Are you able to go the bathroom alone or do you need assistance?" If the person's reply judging his or her own ability is consistent with what the nurse views during the assessment scored 0.

If the person's response is **not consistent** with the nursing orders or if the person response is **unrealistic**, then the patient is considered to **overestimate his or her own abilities** and to be forgetful of limitations and scored as 10.

Assessment is repeated after any new fall.

<u>Scoring and Risk Level:</u> The score is then tallied and recorded on the persons. Risk level and recommended actions (e.g. no interventions needed, standard fall prevention interventions, high risk prevention interventions) are then identified.

Item	Scale	Scoring
History of falling; immediate or within 3	No = 0	Beoring
months	Yes = 5	
Secondary Medical diagnosis	No = 0 Yes = 5	
Ambulatory aid Bed rest/nurse assist Crutches/cane/walker Furniture	None = 0 One or more = 10	
Two or more medications that cause sedation	No = 0 Yes = 5	
Gait/Transferring Normal/bedrest/immobile Weak Impaired	None = 0 Weak = 5 Gait impaired = 10	
Mental status Oriented to own ability. Forgets limitations	None = Forgets, Altered reality = 10	
	Total	

Risk Level	Score	Action
No Risk	0 - 4	Good Basic Nursing Care
Moderate Risk	5 - 15	Implement Standard Fall Prevention Interventions
High Risk	≥ 15	Implement High Risk Fall Prevention Interventions

Nurse Delegation Program AIMs Instructions

There are two parallel procedures, the examination procedure, which tells the person what to do, and the scoring procedure, which tells the clinician how to rate what he or she observes.

Examination Procedure

Either before or after completing the examination procedure, observe the person unobtrusively at rest (e.g., in the waiting room).

The chair to be used during the assessment should be a firm one without arms.

- 1. Ask the person whether there is anything in his or her mouth (such as gum or candy) and, if so, to remove it.
- 2. Ask about the 'current' condition of the patient's teeth. Ask if he or she wears dentures. Ask whether teeth or dentures, bother the person 'now'.
- 3. Ask whether the person notices any movements in his or her mouth, face, hands, or feet. If yes, ask them to describe them and to indicate to what extent the movements 'currently' bother the person or interfere with activities.
- 4. Have the person sit in the chair with hands on knees, legs slightly apart, and feet flat on floor. (Look at the entire body for movements while they sit in this position.)
- 5. Ask the person to sit with hands hanging unsupported if male, between his legs, if female and wearing a dress, hanging over her knees. (Observe hands and other body areas).
 - 6. Ask the person to open his or her mouth. (Observe the tongue at rest within the mouth.)
 - 7. Ask them to stick out his or her tongue. (Observe abnormalities of tongue movement.)
- 8. Using one hand at a time, ask the person to take his or her thumb and touch it to each finger as fast as they can until you say stop. (Observe facial and leg movements during this activity for 10 to 15 seconds.) Repeat activity with other hand.
- 9. Ask the person to stretch both arms straight out in front of them. Ask them to bend one arm up toward their body while keeping the other arm extended. Then have them extend the arm back to original position and repeat with the other arm. Rest arms by side.
- 10. Ask the person to extend both arms out in front, palms down. (Observe trunk, legs, and mouth.)
 - 11. Ask them to stand up. (Observe their profile)
- 12. Have them to walk a few paces, turn, and walk back to the chair. (Observe hands and gait.) Do this twice.

Scoring Procedure

Complete the examination procedure before making ratings.

For the movement ratings (the first three categories below), rate the highest severity observed.

0 = none, 1 = minimal (may be extreme normal), 2 = mild, 3 = moderate, and 4 = severe. According to the original AIMS instructions, one point is subtracted if movements are seen only on activation, but not all investigators follow that convention.

Facial and Oral Movements

1. Muscles of facial expression, e.g., movements of forehead, eyebrows, periorbital area, cheeks.

Include frowning, blinking, grimacing of upper face.

01234

2. Lips and perioral area, e.g., puckering, pouting, smacking.

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3. Jaw, e.g., biting, clenching, chewing, mouth opening, lateral movement.

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4. Tongue. Rate only increase in movement both in and out of mouth, not inability to sustain movement.

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Extremity Movements

5. Upper (arms, wrists, hands, fingers). Include movements that are choreic (abrupt, rapid, brief, jerky, irregular, spontaneous) or athetoid (slow, irregular, usually seen in Cerebral Palsy). <u>Do not include tremor (repetitive, regular, rhythmic movements).</u>

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6. Lower (legs, knees, ankles, toes), e.g., lateral knee movement, foot tapping, heel dropping, foot squirming, inversion, and eversion of foot.

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Trunk Movements

7. Neck, shoulders, hips, e.g., rocking, twisting, squirming, pelvic gyrations. Include diaphragmatic movements.

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Global Judgments

- 8. Severity of abnormal movements.
 - 01234

based on the highest single score on the above items.

- 9. Incapacitation due to abnormal movements.
 - 0 = none, normal
 - 1 = minimal
 - 2 = mild
 - 3 = moderate
 - 4 = severe
- 10. Person's awareness of abnormal movements.
 - 0 = no awareness
 - 1 = aware, no distress
 - 2 = aware, mild distress
 - 3 = aware, moderate distress
 - 4 = aware, severe distress

Dental Status

- 11. Current problems with teeth and/or dentures.
 - $0 = n_0$
 - 1 = yes
- 12. Does this person usually wear dentures?
 - 0 = no
 - 1 = yes



----- NOTE: THIS ALERT IS AN UPDATE TO THE ALERT DATED March 4, 2024 -----

March 7, 2024

TO: Pharmacies, Physicians, Physician Assistants, Nurse Practitioners, Oral Surgeons, Optometrists, Dentists, FQHCs, RHCs, Mental Health Service Providers, and Nursing Homes

RE: Opioid Cumulative Daily Morphine Milligram Equivalents (MME) Limit - MME Decrease

Effective April 1, 2024, the Alabama Medicaid Agency (Medicaid) will implement hard edits on cumulative daily MME claims exceeding 120 MME/day. A phase-in period for claims exceeding 90 MME/day, but less than 120 MME/day, will also be implemented.

Higher doses of opioids are associated with higher risk of overdose and death - even relatively low dosages (20-50 MME per day) may increase risk. Therefore, Medicaid will limit the amount of cumulative MME allowed per day on opioid claims. The edit began at 250 cumulative MME per day and has been gradually decreased over time. The final cumulative MME target is scheduled to be 90 MME per day.

Hard Edit Implementation (Greater than 120 MME);

Effective April 1, 2024, opioid claims that exceed a cumulative MME of 120 MME/day will be denied. The universal PA 0009996324 will no longer be valid to bypass the 120 MME edit. Pharmacy override requests for quantities exceeding the MME limit may be submitted to Kepro and will be reviewed for medical necessity. See the link below for an override form.

Phase-In Period (90 MME - 120 MME):

Effective April 1, 2024, claims that exceed the cumulative daily MME limit of 90 MME/day will be denied. The dispensing pharmacist will be provided a universal prior authorization (PA) number on the rejection screen and may enter this universal PA number on the claim to allow it to be paid. Pharmacists are urged to notify the affected patient/prescriber to develop a plan to decrease the patient's total daily MME.

Edit Details:

- The universal PA number to override the 90 MME (but less than 120 MME) edit will be 0009996325.
- The universal PA number will be provided on each cumulative MME rejection screen for the pharmacist's convenience.
- Additional edits, such as therapeutic duplication, maximum quantity limitations, early refill, non-preferred edits, etc., will still apply.
- Claims prescribed by oncologists will bypass the edit.
- · Long term care and hospice recipients are excluded.
- Children are included in the edit.
- A Recipient Information Sheet for prescribers and pharmacists to provide to recipients can be found at http://www.medicaid.alabama.gov/content/4.0 Programs/4.3 Pharmacy-DME.aspx.
 - ¹ CDC Clinical Practice Guideline for Prescribing Opioids for Pain United States, 2022 I MMWR

ALERT

Anticipated Phase Down:

Medicaid plans to gradually decrease the daily cumulative MME limit to the target of 90 MME/day. The next decrease will be a hard edit on claims exceeding 90 MME/day with no universal override available. Medicaid anticipates implementation of the next edit to occur on July 1, 2024. The Agency recommends providers refer to the most current ALERT for guidance. **Again, pharmacists are urged to notify the affected patient/prescriber to develop a plan to decrease the patient's total daily MME**.

Examples of MME calculations/day include:

- 10 tablets per day of hydrocodone/acetaminophen 5/325 = 50 MME/day
- 6 tablets per day of hydrocodone/acetaminophen 7.5/325 = 45 MME/day
- 5 tablets per day of hydrocodone/acetaminophen 10/325 = 50 MME/day
- 2 tablets per day of oxycodone 15 mg = 45 MME/day
- 3 tablets per day of oxycodone 10 mg = 45 MME/day
- 4 tablets per day of tramadol 50 mg= 40 MME/day*
- 1 patch per 3 days of fentanyl 25mcg/hr= 60 MME/day

A link with more information regarding MME calculations is provided below.

<u>Opioid National Drug Code and Oral MME Conversion File Update | Opioids | CDC</u>

*Please note tramadol MME conversion updated from 0.1 to 0.2 per CDC recommendations.

A link to the U.S. Department of Health and Human Services Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics can be found at https://medicaid.alabama.gov/documents/4.0 Programs/4.3 Pharmacy-DME/4.3 HHS Guidance Dosage Reduction Discontinuation Opioids 10-28-19.pdf.

IMPORTANT: Only when the override is denied will the excess quantity above the maximum unit limit be deemed a non-covered service. Then the recipient can be charged as a cash recipient for that amount in excess of the limit. A prescriber must not write separate prescriptions, one to be paid by Medicaid and one to be paid as cash, to circumvent the override process. FAILURE TO ABIDE BY MEDICAID POLICY MAY RESULT IN RECOUPMENTS AND/OR ADMINISTRATIVE SANCTIONS. Source: Provider Billing Manual 27.2.3

Override Requests:

Once the hard edit is implemented, the MME Cumulative Daily Override Form will be used by the prescriber when requesting an override. The form can be found at: http://medicaid.alabama.gov/content/9.0 Resources/9.4 Forms Library/9.4.13 Pharmacy Forms.aspx.

Any policy questions concerning this provider ALERT should be directed to the Pharmacy Program at (334) 242-5050.

X XXXX	
MedWatch - The FDA Safety Information and Adverse Event Reporting Program	n
	3

TOPIC: Equate Lubricant Eye Ointment, Equate Stye Lubricant Eye Ointment, CVS Health Lubricant Eye Ointment, Lubricant PM Ointment by Brassica Pharma: Recall - Due to Potential Lack of Sterility

AUDIENCE: Consumer, Health Professional, Pharmacy, Ophthalmology

ISSUE: Brassica Pharma Pvt. Ltd. is recalling eye ointment products with an expiration date ranging from February 2024 to September 2025. The products are being recalled due to lack of sterility assurance at the facility noted during an inspection conducted by the FDA.

Risk Statement: For those patients who use these products, there is a potential risk of eye infections or related harm. These products are intended to be sterile. Ophthalmic drug products pose a potential heightened risk of harm to users because drugs applied to the eyes bypass some of the body's natural defenses.

To date, Brassica Pharma Pvt. Ltd. has not received any reports of adverse events up to February 16, 2024 related to this recall.

These products were distributed nationwide to wholesalers, retailers, and via the product distributor, Walmart, CVS and AACE Pharmaceuticals Inc.

For more information about this recall, click on the red button "Read Recall" below.

BACKGROUND: The products being recalled are marketed for dry eye relief or for temporary relief of discomfort due to irritation, stinging, burning and itching.

RECOMMENDATIONS:

 Consumers should stop using the recalled eye ointment and may return any of the above listed products to the place of purchase.

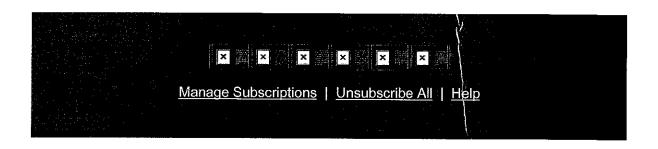
- Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product.
- Consumers, distributors and retailers that have any product which is being recalled should cease distribution of the product.
- Consumers with questions regarding this recall can contact Brassica Pharma Pvt. Ltd. at +1-833-225-9564 or info@brassicapharma.com.

Health professionals and consumers are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and <u>submit the report online</u>.
- <u>Download form</u> or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.



Follow us on X at @FDAMedWatch



This email was sent to melanie.williams@mh.alabama.gov using GovDelivery Communications Cloud on behalf of: U.S. Food and Drug Administration

10903 New Hampshire Ave \cdot Silver Spring, MD \cdot 20993-0002 \cdot 1-888-INFO-FDA



Marks, Angela

From:

Williams, Melanie

Sent:

Tuesday, February 27, 2024 10:55 AM

To:

Jackson, Beverly; Howard, Deidra; Jackson, Vickie; Kane, Linda; Marks, Angela; Perry,

Brenda; Wells, Andriea

Subject:

FW: FDA MedWatch - Equate Lubricant Eye Ointment, Equate Stye Lubricant Eye Ointment, CVS Health Lubricant Eye Ointment, Lubricant PM Ointment by Brassica

Pharma

Follow Up Flag: Flag Status:

Follow up Flagged

FYI.

Melanie Williams
DD Provider Certification



Alabama Department of Mental Health connecting mind and wellness 334-242-0441 (phone) 334-242-0542 (fax)

melanie.williams@mh.alabama.gov

Division of Developmental Disabilities Services

RSA Union Building

100 North Union Street, Suite 486

P.O. Box 301410

Montgomery, AL 36130-1410

www.mh.alabama.gov







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From: U.S. Food and Drug Administration <usfda@public.govdelivery.com>

Sent: Monday, February 26, 2024 6:32 PM

To: Williams, Melanie <melanie.williams@mh.alabama.gov>

Subject: FDA MedWatch - Equate Lubricant Eye Ointment, Equate Stye Lubricant Eye Ointment, CVS Health Lubricant

Eye Ointment, Lubricant PM Ointment by Brassica Pharma

If your email program has trouble displaying this email, view as a webpage.

APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control:	538	
Department or Agency:	Alabama Medical Cannabis Commission	
Rule No.:	Chapter 538-X-2	
Rule Title:	Regulation of Patients and Caregivers	
Intended Action	Amend	
Would the absence of the propendanger the public health,	posed rule significantly harm or welfare, or safety?	No
Is there a reasonable relation power and the protection of t	onship between the state's police the public health, safety, or welfare?	Yes
Is there another, less restrithat could adequately protect	ictive method of regulation available t the public?	No
Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved?		No
To what degree?: N/A		
Is the increase in cost more that might result from the ab	harmful to the public than the harm osence of the proposed rule?	NA
Are all facets of the rule-ma purpose of, and so they have, protection of the public?	king process designed solely for the as their primary effect, the	Yes
Does the proposed action rela litigation which the agency i matter of the proposed rule?	te to or affect in any manner any s a party to concerning the subject	No
Does the proposed rule have a	n economic impact?	No
If the proposed rule has an eaccompanied by a fiscal note part of the second se	conomic impact, the proposed rule is required prepared in accordance with subsection (f) of $\underline{5}$.	to be Section
Certification of Authorized Of		
rem ene reduttements of chabi	roposed rule has been proposed in full compliter 22, Title 41, <u>Code of Alabama 1975</u> , and t ling requirements of the Administrative Proce ervices Agency.	Territoria de la compansión de la compan
Signature of certifying office	o o to o / new	H E ∩
Pate	John McMillan REC'D&F Sunday, March 17, 2024 MAR 18, 202	

LEGISLATIVE SVC AGENCY

ALABAMA MEDICAL CANNABIS COMMISSION

NOTICE OF INTENDED ACTION

AGENCY NAME:

Alabama Medical Cannabis Commission

RULE NO. & TITLE:

Chapter 538-X-2

Regulation of Patients and

Caregivers

INTENDED ACTION:

Amend

SUBSTANCE OF PROPOSED ACTION:

Revisions to existing administrative rules to address potential statutory conflicts.

TIME, PLACE AND MANNER OF PRESENTING VIEWS:

A public comment portal will be available on the Commission's website (www.amcc.alabama.gov) between the date of publication (3/29/2024) and for a period of 35 days thereafter (ending on 5/3/2024).

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Friday, May 3, 2024

CONTACT PERSON AT AGENCY:

Justin C. Aday

John McMillan

John McMillan

(Signature of officer authorized to promulgate and adopt rules or his or her deputy)

ALABAMA MEDICAL CANNABIS COMMISSION ADMINISTRATIVE CODE

CHAPTER 538-X-2 REGULATION OF PATIENTS AND CAREGIVERS

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538-X-2-.01 Purpose.

This Chapter is promulgated to regulate qualified Patients and Caregivers in registering for, obtaining, and administering medical cannabis and in interacting with registered certifying physicians.

Author: William H. Webster

Statutory Authority: <u>Code of Ala. 1975</u>, §\$20-2A-22, as amended. History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.02 Definitions.

As set forth in this Chapter, the following definitions apply

(1) "Administer" or "administration." The introduction of medical cannabis into the body of a human, whether through use of an inhaler, ingestion, or any other approved means, whether by a registered qualified patient (self-

administration), a registered qualified caregiver, or (improperly) by another.

- (2) "Professional Caregiver." Someone whose career is to assist another person in a way that enables them to live as independently as possible. For the purposes of these Rules, a professional caregiver must be (A) over 21 years of age and (B) (1) licensed, having passed a basic screening test provided by the Alabama Medicaid Agency in collaboration with the Alabama Department of Rehabilitation Services and the Alabama Department of Senior Services); (2) certified by the American Caregiver Association; or (3) employed as a nurse, therapist or other healthcare provider by a hospital, long term care facility or hospice program licensed under Alabama law.
- (3) (2) Refuse to grant or renew." As used in this Chapter, to deny original or continued registration for a period of at least twelve months. After twelve months or such period of time as the individual Commission order may require, a patient or caregiver or an individual who desires to attain such status by registration, and whose registration the Commission has refused to grant or renew, may make application to the Commission for issuance of a new registration in accordance with the Act and this Chapter. An individual who desires to attain patient or caregiver status by registration and whose registration the Commission has refused to grant or renew must satisfy all requirements established by the Commission.
- (4) (3) "Revoke." As used in this Chapter, to take action against a patient's or caregiver's registration, rendering such registration void; such registration may not be reissued. "Revoke" is an action that is permanent against the registration and the patient or caregiver.
- (5)(4) "Stale Registration." A submission to register as a patient or caregiver whereby the submitting party fails to complete all submission requirements within 60 calendar days of the initiation of a registration by a registered certifying physician, and after being notified by the Commission, subject to the factors that would otherwise remove the submitter from consideration under the Act and this Chapter. An individual forfeits all fees associated with a stale registration submission. The Commission shall not be required to act on, and may destroy, any stale registration submission. If the registration is stale, the submitter shall be required to reapply for registration in accordance with the Act and this Chapter, in effect at the time of resubmission.

- +(6) "Suspend." To take action against a registration, rendering such registration without force and effect for a period of time as determined by the Commission.
- (7) (6) "Under the Influence of Medical Cannabis." At a level that would cause the user to be violation of current State law as it pertains to marijuana (cannabis).

Author: William H. Webster; Justin C. Aday

Statutory Authority: Code of Ala. 1975, \$\$20-2A-22, as amended. History: New Rule: Published August 31, 2022; effective October

15, 2022. Amended: Published ; effective

538-X-2-.03 Requisite Conditions To Qualify As A Registered Qualified Patient.

- (1) Before medical cannabis may be dispensed to, possessed by, or administered to a prospective patient and, if applicable, the prospective patient's caregiver, the patient and caregiver, must be placed on the patient registry established by the Commission in accordance with the Act and this Chapter.
- (2) A registered qualified patient 19 years of age or older or a registered caregiver acting on behalf of a registered qualified patient is not subject to arrest or prosecution for unlawful possession of marijuana, if (a) possessing no more than 70 daily dosages of medical cannabis for such registered qualified patient, and (b) having a valid medical cannabis card.

(3) Adult Patients

- (a) A resident of this state who is 19 years of age or older is a registered qualified patient if meeting all of the following conditions:
 - 1. Has been certified by a registered certifying physician as having a qualifying medical condition and has been recommended for the use of medical cannabis by a registered certifying physician.
 - 2. Is registered with the Commission, having been placed on the patient registry established by the Commission in accordance with the Act and this Chapter.
 - 3. Has been issued a valid medical cannabis card by the Commission.
- (b) Upon meeting the foregoing conditions, such registered qualified patient may purchase, possess and use medical

cannabis, subject to the limitations of \$20-2A-30(d), Code of Ala. 1975, (as amended), relating to maximum medical dosage.

(4) Minor Patients

- (a) A resident of this state who is under the age of 19 years is a registered qualified patient if meeting all of the following conditions:
 - 1. Has been certified by a registered certifying physician as having a qualifying medical condition and has been recommended to use medical cannabis by the registered certifying physician.
 - 2. Is registered with the Commission, having been placed on the patient registry established by the Commission in accordance with the Act and this Chapter.
 - 3. Has a qualified caregiver who is (A) the patient's parent, legal guardian, grandparent, spouse, authorized professional caregiver, or an individual with a valid power of attorney for healthcare of the minor; (B) a resident of this state; and (C) possesses a valid caregiver's medical cannabis card issued by the Commission.
- (b) Upon meeting the foregoing conditions, such minor patient may use medical cannabis obtained by a caregiver on behalf of the minor patient, but the minor patient may not purchase or possess medical cannabis. Notwithstanding the foregoing, a minor patient may not legally use medical cannabis with a potency greater than three percent (3%) tetrahydrocannabinol.

Author: William H. Webster; Justin C. Aday

Statutory Authority: Code of Ala. 1975, \$\$20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022. Amended: Published ; effective ____.

538-X-2-.04 Caregiver Qualifications.

- (1) A resident of this state is a registered caregiver if he or she meets all of the following conditions:
 - (a) Is registered with this Commission, having been identified to a patient who has been placed on the registry established by the Commission in accordance with the Act and this Chapter.

- (b) Has been issued a valid medical cannabis card by the Commission.
- (c) Is at least 21 years of age or the parent or legal guardian of, and caregiver for, a registered qualified patient.
- (d) Is the patient's parent, legal guardian, grandparent, spouse, authorized professional caregiver, or an individual with a valid power of attorney for healthcare of a registered qualified patient.
- (2) A registered caregiver described above may purchase and possess medical cannabis on behalf of a registered qualified patient to whom the registered caregiver has been identified in the patient registry and may administer medical cannabis to the patient or patients to whom the registered caregiver has been identified. A registered caregiver may not use medical cannabis unless the registered caregiver is also a registered qualified patient pursuant to r. 538-x-2-.03.

Author: William H. Webster; Justin C. Aday

Statutory Authority: Code of Ala. 1975, \$\$20-2A-22, as amended. History: New Rule: Published August 31, 2022; effective October 15, 2022. Amended: Published ; effective

538-x-2-.05 Patient Registration.

- (1) To qualify for placement on the registry, a prospective patient must:
 - (a) Be an Alabama resident.
 - (b) Establish and maintain a bona fide physician-patient relationship with a registered certifying physician who (acting individually or through a designated representative) shall submit a complete patient registration submission.
 - (c) Become certified by a registered certifying physician who has diagnosed or confirmed a qualifying condition and has recommended the patient's use of medical cannabis.
 - (d) Consent to treatment with medical cannabis. If the patient is a minor or individual with a court-appointed legal guardian, the prospective patient's parent or legal guardian shall consent to treatment with medical cannabis.
 - (e) Remit to the Commission the application fee as set by the Commission.

- (2) Only a patient, a patient's caregiver, or a registered certifying physician with whom a prospective patient has a bona fide physician-patient relationship (acting individually or through the physician's designated representative) shall submit the patient registration. For a registration submission related to a patient who is 19 years of age or older to be considered complete, a completed certification from a registered certifying physician, applicable patient registration fee, and the following items must be submitted to the Patient Registry, notwithstanding but in addition to any that may otherwise be required by the Board of Medical Examiners:
 - (a) Patient's full name, residential address, telephone number, date of birth, and electronic mailing address.
 - (b) If applicable, caregiver's full name, residential address, telephone number, date of birth, and electronic mailing address.
 - (c) Patient's government-issued identification (such as a driver's license, Alabama Identification Card or Social Security Card). Patients must present a registered certifying physician with an unexpired driver's license, unexpired Alabama Identification Card, unexpired passport, Social Security Card, Birth Certificate, or other documentation proving identity as may be approved by the Commission.
 - (d) A digital color photograph of the patient taken no more than 30 days prior to submission of the patient registration.
 - (e) Registered certifying physician's full name (first name and last name); specialty; professional entity or affiliation, if any; business street address; telephone number; and email address.
 - (f) Registered certifying physician's Alabama Medical Cannabis Certification Permit Identification Number and medical license number issued by the State Board of Medical Examiners.
 - (g) Date medical cannabis certification was issued by the registered certifying physician.
 - (h) Indication whether the certification is new or a renewal.
 - (i) The following written attestations of the prospective patient or caregiver:

- 1. That the registered certifying physician has explained the possible risks and benefits associated with the use of medical cannabis;
- 2. That the registered certifying physician has obtained the patient's or caregiver's consent to treatment with medical cannabis; and
- 3. That the patient has agreed to comply with the provisions of the Act and this Chapter.
- (j) The following written attestations of the registered certifying physician:
 - 1. That the prospective patient has a bona-fide patient-physician relationship with, and is currently under the care of, the registered certifying physician;
 - 2. That the prospective patient has a qualifying medical condition under the Act; naming the condition; and if a terminal illness, specifying the terminal illness;
 - 3. That conventional medical treatment or therapy has failed (as defined further below), or that use of cannabis is the standard of care under the circumstances;
 - 4. That the patient is suitable to receive treatment or therapy through the use of medical cannabis;
 - 5. That the registered certifying physician has complied with all requirements imposed by the Rules promulgated by the State Board of Medical Examiners; and
 - 6. That the patient or caregiver has provided voluntary informed written consent as to the following matters required by \$20-2A-33(5), Code of Ala. 1975, (as amended):
 - (i) The federal and state classification of cannabis as a Schedule I controlled substance.
 - (ii) The approval and oversight status of cannabis by the Food and Drug Administration.
 - (iii) The current state of research on the efficacy of cannabis to treat the qualifying medical condition or conditions.
 - (iv) The potential for addiction.

- (v) The potential effect that cannabis may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require an individual to be alert or respond quickly.
- (vi) The potential side effect of cannabis use.
- (vii) The risks, benefits, and drug interactions of cannabis.
- (viii) A statement that the use of medical cannabis could result in termination from employment without recourse and those costs may not be covered by insurance or government programs.
- (ix) That the patient's de-identified health information contained in the patient's medical record, patient registry may be used for research purposes or used to monitor compliance with this Chapter, as further provided in \$20-2A- 35(c), Code of Ala. 1975, (as amended).
- (k) Such other information as the Commission may reasonably require, as set forth on the patient registry form.
- (3) If a prospective patient is younger than 19 years of age or has a court-appointed legal guardian, a patient registration submission is incomplete unless it is accompanied by a caregiver registration submission in accordance with the Act and this Chapter. Patients who become 19 years of age while their prior registration remains valid may apply for a new registration either immediately or in accordance with the renewal process under paragraph 9. of this rule. A submission from a patient that includes all information found in paragraph 2. of this rule shall be considered complete.
- (4) A complete patient registration submission must be received by the Commission within 60 calendar days of the date of certification by the registered certifying physician. Failure to comply with this requirement results in a "stale registration" as defined in this Chapter and renders the recommendation void.
- (5) If a registration submission is determined to be inaccurate or incomplete, the Commission shall note a deficiency on the patient registry and send the prospective patient notice of the deficiency. If the deficiency is not corrected within 60 calendar days from the date the registration was submitted, the lack of

progress on the submission results in a "stale registration" as defined in this Chapter and renders the recommendation void.

- (6) Prospective patients must provide proof of Alabama residency to their registered certifying physician or the physician's representative during the registration submission process. Proof of Alabama residency shall include one of the following:
 - (a) The prospective patient's unexpired Alabama driver's license;
 - (b) The prospective patient's unexpired Alabama identification card issued by the Alabama Law Enforcement Agency (ALEA);
 - (c) The prospective patient's unexpired United States Passport demonstrating Alabama residency;
 - (d) A current certificate of enrollment from a qualified Alabama public or private educational institution; or
 - (e) Any other identification (e.g., military I.D.), proving Alabama residency as approved by the Commission.
- (7) A patient registration shall be valid from the date of issuance and expire one year later.
- (8) The Commission shall send a notification to each patient 45 calendar days before the expiration date on the patient's medical cannabis card.
- (9) To maintain a valid patient registration, a patient must annually renew, before the expiration date stated on the patient's medical cannabis card. Renewal submissions, fees, and required documentation must be submitted not less than 14 calendar days before the expiration date on the patient's medical cannabis card. Failure to renew a patient registration will result in an automatic expiration of the medical cannabis card. Author: William H. Webster

Statutory Authority: <u>Code of Ala. 1975</u>, §\$20-2A-22, as amended. History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.06 <u>Caregiver Registration</u>.

(1) Unless otherwise provided in paragraph 2. of this rule, only Alabama residents who are natural persons 21 years of age or

- older may register with the Commission to serve as a caregiver for a qualifying patient.
- (2) Notwithstanding the age limitation in paragraph 1. of this rule, a minor patient's parent or legal guardian 19 years of age or older and who otherwise meets the requirements of the Act and this Chapter, may serve as the minor patient's caregiver.
- (3) No person shall serve as a caregiver for any patient before registering with the Commission as provided in the Act and this Chapter.
- (4) A patient shall designate no more than two caregivers. The Commission shall register no more than two caregivers for each patient.
- (5) A competent adult patient may change caregivers with 14 days' written notice to the certifying physician, who (acting individually or through a designated representative) shall notify the Commission of the change on the patient registry.
- (6) An individual shall serve as a caregiver for no more than three patients. Except as provided in paragraph 8. of this rule, the Commission shall associate no more than three patients for each caregiver.
- (7) A caregiver must possess a medical cannabis card, and pay an application fee, for each patient for whom the caregiver provides care.
- (8) Notwithstanding the limitations in paragraphs 4. and 6. of this Rule, upon a written request, the Commission may, in its discretion, permit an individual to serve as a caregiver for more than three patients and/or for a patient to designate more than two caregivers:
 - (a) In order to avoid unnecessary hardship to the patient or patients;
 - (b) Where the patients' care is being provided in a hospital, long-term care facility, or through a hospice program licensed under Alabama law; or
 - (c) Where the caregiver is simultaneously caring for multiple patients who reside in the same household as the caregiver.
- (9) Except upon a demonstration of extraordinary circumstances and with the express permission of the Commission, an individual caregiver may not serve in such capacity as to more than ten patients simultaneously.

- (10) If a patient requests permission to change a caregiver before renewal, the licensed certifying physician or the physician's representative shall note the request on the patient registry, setting forth information relating to the proposed caregiver, so as to conform with the caregiver registration requirements under the Act and this Chapter. The Commission shall approve a new caregiver only if such individual meets the requirements of the Act and this Chapter.
- (11) A patient's licensed certifying physician shall not serve as the patient's caregiver.
- (12) The Commission shall deny a submission for a caregiver registration if the individual identified on the submission is included in one or more of the following databases:
 - (a) The list of excluded individuals and entities maintained by the office of inspector general in the United States Department of Health and Human Services pursuant to 42 U.S.C. part 1320a-7 (as amended) and 42 U.S.C. part 1320c-5 (as amended) (i.e., indicating that the individual has been sanctioned for or convicted of fraud, theft or other dishonest and illegal conduct with respect to Medicare or other Government agencies related to healthcare).
 - (b) The Alabama Department of Human Resources' online registry of individuals who have been determined to be indicated of abuse.
 - (c) The state or federal sex offender registry.
 - (d) The Alabama Department of Correction's or U.S. Bureau of Prisons' registry of inmates and parolees.
 - (e) Any governmental database indicating that the health care provider seeking caregiver status has neglected or abused a patient, a long-term care facility resident, or residential care facility resident or misappropriated property of any such resident.
- (13) Medical Cannabis may not be possessed by or administered to anyone other than a registered qualified patient, unless the person is a caregiver who is placed on the registry established by the Commission in accordance with the Act and this Chapter. A registered caregiver may possess and administer medical cannabis only to those patients with whom the caregiver's registration is associated.
- (14) An individual who meets the caregiver eligibility requirements under the Act and this Chapter may be registered as

a caregiver if the following are electronically submitted to the Commission through the patient registry:

- (a) Identification of a patient who is registered or attempting to register as a patient pursuant to the Act and this Chapter, and for whom the individual intends to serve as a caregiver;
- (b) Completed caregiver registration information entered into the patient registry in accordance with paragraph 14 of this rule; and
- (c) Required application fee as set by the Commission.
- (15) Only the caregiver, or a licensed certifying physician with whom the patient or prospective patient has a bona fide physician-patient relationship, or the physician's representative, may submit the caregiver's registration. For a caregiver's registration submission to be considered complete, the applicable caregiver registration fee, all of the information supplied as to patients as set forth in 538-x-.05-2. of this Chapter, as well as the following items must be submitted to the Commission in a manner suitable to the Commission:
 - (a) The full name, residential address, telephone number, date of birth, and email address of the caregiver and the associated patient.
 - (b) Associated patient's registration number issued by the Commission, if available.
 - (c) Caregivers government-issued identification number (such as a driver's license number, Alabama Identification Card number or Social Security Number). Caregivers must present a registered certifying physician with an unexpired driver's license, unexpired Alabama Identification Card, unexpired passport, Social Security Card, Birth Certificate, or other documentation proving identity as may be approved by the Commission.
 - (d) A digital color photograph of the caregiver taken no more than 30 days prior to submission of the caregiver registration.
 - (e) Indication whether the caregiver certification is new or a renewal.
 - (f) The following written attestations of the prospective caregiver:

- 1. That the registered certifying physician has explained the possible risks and benefits associated with the use of medical cannabis:
- 2. That the registered certifying physician has obtained the caregiver's consent to treat the patient with medical cannabis; and
- 3. That the caregiver has agreed to comply with the provisions of the Act and this Chapter.
- (g) The following written attestations of the registered certifying physician as to the caregiver, in addition to those relating to the patient under paragraph 2.j. of Rule 538-X-2-.05:
 - 1. That the caregiver is suitable to the patient's treatment or therapy through the use of medical cannabis; and
 - 2. That the caregiver, on behalf of the patient, has provided voluntary informed written consent as to the following matters required by \$20-2A-33(5), Code of Ala. 1975, (as amended):
 - (i) The federal and state classification of cannabis as a Schedule I controlled substance.
 - (ii) The approval and oversight status of cannabis by the Food and Drug Administration.
 - (iii) The current state of research on the efficacy of cannabis to treat the qualifying medical condition or conditions.
 - (iv) The potential for addiction.
 - (v) The potential effect that cannabis may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require an individual to be alert or respond quickly.
 - (vi) The potential side effect of cannabis use.
 - (vii) The risks, benefits, and drug interactions of cannabis.

- (viii) A statement that the use of medical cannabis could result in termination from employment without recourse.
- (ix) A statement that the costs associated with the patient's use of medical cannabis may not be covered by insurance or government assistance programs.
- (x) That the patient's de-identified health information contained in the patient's medical record within the patient registry may be used for research purposes or used to monitor compliance with this chapter, as further provided in \$20-2A-35(c), Code of Ala. 1975, (as amended).
- (h) Such other information as the Commission may reasonably require.
- (16) All prospective caregivers shall attest to the following:
 - (a) That the prospective caregiver meets the qualifications for a caregiver set forth in Rule 538-X-2-.04;
 - (b) That the registered certifying physician has explained to the caregiver the possible risks and benefits associated with the use of medical cannabis;
 - (c) That the prospective caregiver agrees to serve as the caregiver for the patient identified on their registry submission;
 - (d) That the prospective caregiver agrees to control the dosage and frequency of the use of medical cannabis in accordance with any instruction for use provided by the certifying physician; and
 - (e) That the prospective caregiver agrees to comply with the Act and this Chapter.
 - (f) If the patient is under the age of 19, that the prospective caregiver understands the information provided by the certifying physician and knowingly consents to the use of medical cannabis by the patient.
- (17) A caregiver registration shall be valid from the date of issuance and expire one year later.
- (18) The Commission shall send a notification to each caregiver 45 calendar days before the expiration date on the caregiver's medical cannabis card.

(19) To maintain a valid caregiver registration, a caregiver must annually renew the caregiver registration submission, in accordance with this Rule. Renewal applications, fees, and required documentation must be submitted no less than 14 calendar days before the expiration of the caregiver's medical cannabis card.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §\$20-2A-22, as amended. History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.07 Purchase Of Medical Cannabis By Patients And Caregivers.

- (1) A patient or caregiver may only purchase medical cannabis pursuant to a valid and active medical cannabis card, which may be tangible or virtual, demonstrating certification by a registered certifying physician pursuant to the Act and this Chapter.
- (2) Patients under 19 years of age shall be issued a medical cannabis card identifying them as a minor, and such patients are prohibited from purchasing medical cannabis except through a caregiver.
- (3) Requiring patients and caregivers to possess a medical cannabis card lawfully obtained pursuant to the Act and this Chapter does not infringe on the cardholder's state or federal constitutional rights.(\$20-2A-11, Code of Ala. 1975, (as amended)).
- (4) Upon entry into a dispensing site and before purchasing medical cannabis, patients and caregivers must provide their medical cannabis card; at the discretion of the dispensary or integrated facility operating the dispensing site, patients and caregivers also may be asked to provide additional photo or other approved identification, including an unexpired Alabama driver's license, an unexpired Alabama identification card issued by ALEA; passport; or any other identification proving identity as approved by the Commission.
- (5) Any persons, including children or guests of patients or caregivers, who are unable to provide a medical cannabis card matching a valid patient registry profile, or who are unable to provide, upon request, additional identification to the satisfaction of dispensing site personnel, are prohibited from entering the dispensing site. This rule does not apply to employees, representatives of other licensees, Commission members

or personnel or inspectors, third parties visiting the dispensing site at the request of the Commission or the licensee, or who are entering the facility for the purpose of performing repairs or maintenance at the dispensing site.

- (6) The identification number on the medical cannabis card provided to a dispensary employee must be identical to the identification number included in the patient or caregiver's profile in the patient registry.
- (7) Before purchasing medical cannabis, patients and caregivers must provide the dispensing employee their medical cannabis card; at the discretion of the dispensing site, they also may be asked to provide additional identification as described in paragraph 4. of this rule.
- (8) A registered certifying physician does not prescribe medical cannabis but merely sets a recommended form of intake (i.e., oral tablet, capsule, tincture, inhaler, lotion, etc.) and THC content, up to a maximum daily dosage of medical cannabis for the patient based on the patient's diagnosis, qualifying medical condition, age, size, and other individual factors. Such determinations as to form and THC content to be recommended shall be exclusively the province of the registered certifying physician, up to the maximum daily dosage allowed by law, as described in paragraph 9 of this rule. (\$20-2A-33(f)(1), Code of Ala. 1975, (as amended)).
- (9) Dosages of medical cannabis purchased by a patient or caregiver shall be limited to the lower of the maximum daily dosage recommended for the patient by the licensed certifying physician, or the maximum daily dosage permitted by law under the Act and this Chapter:
 - (a) As to all patients, regardless of the form of administration or the patient's condition or individual factors, the initial maximum daily dosage recommended by the registered certifying physician may be lower than, but shall not exceed, 50 mg of delta-9 THC.
 - (b) A registered certifying physician who initially sets the maximum daily dosage at a level lower than 50 mg of delta-9 THC may increase the maximum daily dosage, to an amount less than or equal to 50 mg delta-9 THC, subject to subparagraph c., at any time upon review with the patient during a follow-up visit.
 - (c) If 90 days have passed during which the patient has been unsuccessfully treating with medical cannabis while under the registered certifying physician's care, and the registered

certifying physician determines that a higher dosage of medical cannabis, up to 75 mg of delta-9 THC is medically appropriate, a registered certifying physician may increase the maximum daily dosage beyond 50 mg of delta-9 THC, but not to exceed 75 mg of delta-9 THC. (\$20-2A-33(f)(2)a., Code of Ala. 1975, (as amended)).

- (d) A registered certifying physician may increase the maximum daily dosage beyond 75 mg of delta-9 THC at any time the patient has been diagnosed with a terminal illness, but only after the registered certifying physician notifies the patient that the patient's driver's license will be suspended. (§ 20-2A-33(f)(2)b., Code of Ala. 1975, (as amended)).
- (e) A registered certifying physician may not lawfully recommend the use of medical cannabis with a potency greater than three percent (3%) tetrahydrocannabinol to any minor for any qualifying medical condition. A minor may not legally use medical cannabis with a potency greater than three percent (3%) tetrahydrocannabinol, whether or not the minor has a valid medical cannabis card. The caregiver of a minor who holds a medical cannabis card may not legally possess medical cannabis with a potency greater than three percent (3%) tetrahydrocannabinol, unless the caregiver holds a medical cannabis card based on their own qualifying medical condition or holds a caregiver medical cannabis card on behalf of a patient who is not a minor.
- (10) Notwithstanding the foregoing, the number of daily doses of medical cannabis that may be purchased by a patient or caregiver at one time shall be limited to the lesser of:
 - (a) a 60-day supply; or
 - (b) the number of doses equal to the number of days since the patient's or caregiver's last purchase of medical cannabis; or
- (c) as recommended by the registered certifying physician.

 Author: William H. Webster

 Statutory Authority: Code of Ala. 1975, \$\$20-2A-22, as amended.

 History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.08 Restrictions On Patients And Caregivers.

(1) Patient and caregiver registrations are non-transferrable.

- (2) Patients and caregivers shall not engage in the cultivation of medical cannabis or the manufacture of medical cannabis extract. Registration as a patient or caregiver is not a license under the Act or this Chapter to cultivate, produce, transport, or dispense medical cannabis.
- (3) No patient or caregiver shall provide or accept samples of medical cannabis.
- (4) Patients and caregivers shall purchase medical cannabis only from a certified medical cannabis dispensing site operated by a dispensary or integrated facility licensed by the Commission.
- (5) Patients and caregivers shall store medical cannabis in a secure location so as to prevent theft, loss, or access by persons not authorized under the Act and this Chapter.
- (6) Patients and caregivers shall carry their medical cannabis cards with them whenever they are in possession of medical cannabis. No more than a 70-day supply of medical cannabis, as then recommended by the patient's registered certifying physician, may be possessed by or on behalf of a single patient at any time.
- (7) Medical cannabis shall be maintained in one of the following containers at all times until administered to, or by, a patient:
 - (a) The original dispensing package with an unaltered dispensary label in accordance with the Act and these Rules; or
 - (b) A container for storing medical cannabis provided by a dispensary or integrated facility in accordance with the Act and these Rules.
- (8) Medical cannabis shall not be possessed or administered on federal property or in federal buildings.
- (9) Medical cannabis shall not be possessed or administered at state or federal correctional detention facilities, including but not limited to prisons and juvenile detention centers.
- (10) Medical cannabis shall not be possessed or administered in any public or private place where medical cannabis is prohibited.
- (11) Medical cannabis shall not be administered or possessed outside of its packaging on the premises of a dispensing site or any other licensed facility under the Act or these Rules.

- (12) No patient shall operate a motor vehicle, watercraft, heavy machinery, or aircraft while under the influence of medical cannabis.
- (13) A caregiver may receive compensation for services provided as a caregiver in addition to reimbursement for reasonable expenses incurred in the provision of services as a caregiver.
- (14) The Commission shall notify patients and caregivers upon the expiration of the patient's or caregiver's registration, or if the patient's registration is suspended or revoked. In such event, patients, caregivers and, in the event of death, personal representatives of patients and caregivers, shall dispose of all medical cannabis within seven calendar days after the patient's death or expiration of their registration. Acceptable methods for the disposal of medical cannabis shall be available at the Commission's website.
- (15) An Alabama Medical Cannabis Card is valid only within the State of Alabama and may only be issued to and used by Alabama Residents as defined in these Rules.
- (16) Alabama Medical Cannabis Cards may not be obtained or used by non-residents, even though the non-resident is present in Alabama or is eligible to receive cannabis in any form for any reason under the laws of another jurisdiction.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, \$\$20-2A-22, as amended. History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.09 Voluntary Relinquishment Or Termination Of Medical Cannabis Card.

- (1) At any time, a patient or caregiver may voluntarily relinquish their certification as such by written notification to the certifying physician or the Commission.
- (2) The registered certifying physician or the physician's designated representative shall inform the Commission by notation on the patient registry within 72 hours of (1) receiving written notification of the patient's or caregiver's decision to voluntarily relinquish the patient's or caregiver's medical cannabis certification; (2) determining that a patient is no longer under a diagnosis of a qualifying condition; (3) being notified of the death of the patient or caregiver; or (4) learning that the caregiver has quit, been terminated, or for any

other reason is no longer acting as caregiver with respect to the patient.

- (3)—The employer of a professional caregiver employed by a hospital, long term care facility or hospice program licensed under Alabama law shall inform the Commission by notation on the patient registry within 72 hours of (1) being notified of the death of the patient or caregiver; or (2) learning that the caregiver has quit, been terminated, or for some other reason is no longer acting as caregiver with respect to the patient.
- (4)-(3) A patient or caregiver may, upon learning from a licensed certifying physician that the patient no longer has a diagnosis of a qualifying condition:
 - (a) Inform the Commission, by notation on the patient registry, of the patient's intention to dispute or obtain documentation of an alternate qualifying condition (resulting in the suspension and not the revocation of the patient's certification):
 - (b) Obtain and cause to be submitted, within 30 days, documentation from another qualified licensed certifying physician that, despite the prior physician's change in diagnosis, the patient has a diagnosis of a qualifying condition; however, failure to submit the required documentation within 30 days shall result in the revocation of the patient's certification, thereafter requiring full documentation and payment of the application fee to resubmit.
- (5) (4) No patient or caregiver may maintain an active registration (as demonstrated by a valid medical cannabis card) without an active diagnosis of a qualifying medical condition as provided in the Act or these Rules. Medical cannabis shall not be purchased or otherwise obtained without an active certification from a licensed certifying physician as demonstrated by a valid medical cannabis card. A suspended certification prohibits the patient or caregiver from possessing, ingesting, administering, or purchasing medical cannabis.
- (6)(5) If a patient's medical cannabis card has been suspended or revoked, the medical cannabis card of the patient's caregiver applicable to that patient if any, likewise shall be suspended or revoked.

Author: William H. Webster; Justin C. Aday

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538-X-2-.10 Circumstances Requiring Notice To The Commission.

- (1) A patient or caregiver must notify the Commission within 72 hours of learning that the patient's or caregiver's medical cannabis card has been lost or stolen, used fraudulently or has otherwise been accessed without authorization. After notification that a medical cannabis card has been lost, stolen, or used fraudulently or has otherwise been accessed without authorization, the Commission may, pursuant to the provisions of this Chapter and the patient's or caregiver's payment of the medical cannabis card replacement fee provided in the Commission's schedule of fees, issue a new medical cannabis card with a new registry number.
- (2) If a patient is deceased, the patient's physician, caregiver, if any, or a legal representative of the patient, shall notify the Commission as soon as possible but not later than 72 hours of learning of the patient's death.
- (3) A patient or caregiver shall report to the Commission within 14 calendar days an arrest, conviction or pendency of the following charges against the patient or caregiver:
 - (a) Any felony offense under the laws of Alabama;
 - (b) Any felony offense under federal law;
 - (c) Any crime under the laws of another jurisdiction that would constitute a felony offense under the laws of Alabama;
 - (d) Any misdemeanor offense under the laws of Alabama, federal law, or the laws of another jurisdiction involving the possession, use, or distribution of illegal drugs; the operation of a motor vehicle, watercraft, or aircraft while under the influence of an illegal substance; or any crime involving fraud, theft, violence, abuse or neglect.
- (4) If a patient has a caregiver, that caregiver may provide any required notification to the Commission on behalf of the patient using the same forms and process in accordance with the Act and this Chapter.
- (5) A patient or caregiver must notify the Commission of any change in information (other than a change in qualifying medical condition or as set forth above) previously provided to the Commission, not later than 72 hours after learning of such change.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §\$20-2A-22, as amended. History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.11 Sanctions.

- (1) The Commission, after notice and hearing in accordance with the Act and these Rules, may impose any one or more of the following sanctions on a patient or caregiver if the Commission finds the individual engaged in any of the conduct set forth in paragraph 2. of this rule:
 - (a) Revoke, suspend, restrict, limit, or refuse to grant or renew the patient's or caregiver's medical cannabis card;
 - (b) Place the patient or caregiver on probation for a period not longer than one year; or
 - (c) Issue a written reprimand to the patient or caregiver and include a notation of the reprimand in the patient registry.
- (2) The Commission may impose the sanctions listed in paragraph 1. of this rule if the Commission finds:
 - (a) The prospective patient or caregiver fails to meet the requirements set forth in the Act and this Chapter;
 - (b) Any information provided to the Commission by the patient or caregiver was false or misleading;
 - (c) The prospective patient's or caregiver's registration submission is, or at any time has been, revoked, suspended, or denied by another jurisdiction;
 - (d) The applicant is a prospective caregiver who has attempted to or did serve as a caregiver for an impermissible number of patients;
 - (e) The caregiver's patient had their patient registration suspended, revoked, or inactivated and the caregiver failed to voluntarily relinquish their caregiver registration;
 - (f) The prospective caregiver attempted to register to serve as a caregiver for a patient whose medical cannabis card or registration has been denied or suspended, either in Alabama or under the laws of another jurisdiction;

- (g) The patient (1) obtained more than the legally permissible supply of medical cannabis during a 60-day period or (2) possessed more than 70 days' supply of medical cannabis at any one time. A legally permissible supply includes the aggregate amount of medical cannabis obtained by all the patient's caregivers;
- (h) The caregiver obtained more than the legally permissible supply of cannabis in a 60- day period on behalf of a single patient;
- (i) The patient is no longer diagnosed with a qualifying condition and the patient or caregiver has failed to voluntarily relinquish the patient's registration and return the medical cannabis card or obtain another diagnosis and provide proper documentation as required by the Act and this Chapter;
- (j) The patient or caregiver failed to report any changes in any information related to the patient or caregiver, other than a change in medical condition, required under the Act and this Chapter within 72 hours of learning of such change;
- (k) The patient or caregiver failed to report actual knowledge of any act or omission by any individual or entity whereby cannabis or medical cannabis was being illegally diverted in violation of the Act or these Rules;
- (1) The patient or caregiver used or maintained medical cannabis in a manner that puts others at risk or failed to take reasonable precautions to avoid putting others at risk;
- (m) The patient or caregiver sold, gave, dispensed or administered a patient's medical cannabis to any other person (i.e., diverted cannabis), including other patients or caregivers);
- (n) The patient or caregiver allowed another person to use the patient's or caregiver's medical cannabis card;
- (o) The patient's or caregiver's medical cannabis card or registration was fraudulently used or improperly accessed by a person without authorization and the patient or caregiver failed to notify the Commission within 72 hours of learning that the card or registry was accessed without authorization;
- (p) The patient consumed medical cannabis using a method of administration that is not permitted by the Act or this Chapter;

- (q) A caregiver administered medical cannabis to a patient using a method of administration that is not permitted under the Act or this Chapter.
- (r) The patient consumed, or the caregiver allowed medical cannabis to be consumed, in a place where consumption is prohibited by the Act or this Chapter;
- (s) The patient or caregiver tampered with, falsified, altered, modified or allowed another person to tamper with, falsify, alter or modify, a patient's or caregiver's medical cannabis card;
- (t) The patient operated a motor vehicle, watercraft, heavy machinery, or aircraft under the influence of medical cannabis;
- (u) The patient or caregiver attempted to or did grow or cultivate, process, or transport cannabis contrary to the Act, these Rules and/or other Alabama law (i.e., illicit cannabis);
- (v) The patient or caregiver knowingly misrepresented any fact or circumstance related to the medical use of cannabis to the Commission, law enforcement, licensed certifying physician, or a dispensary employee.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, \$\$20-2A-22, as amended. Published August 31, 2022; effective October 15, 2022.

538-X-2-.12 Involuntary Suspension Of Certification.

(1) The Commission, acting as a body or through its agents, may suspend a patient's or caregiver's certification to hold a medical cannabis card by using a telephone or video conference call to review the allegations and make its determination. The Commission shall endeavor to hold the telephone or video conference at a mutually agreeable time. The patient's or caregiver's failure to appear for a telephone or video conference call required by the Commission or its agents shall be deemed evidence to support the contemplated suspension. If the Commission, acting as a body or through its agents, in consultation with the recommending physician, determines that there is clear and convincing evidence that the patient's or caregiver's medical cannabis card is being abused, such that continuing to furnish or dispense medical cannabis to the patient or caregiver, presents a danger of immediate and serious harm to

the patient, caregiver, or to others, the Commission may suspend the individual's certification without a hearing, pending final adjudication to determine whether permanent sanctions as set forth in this Chapter are appropriate.

(2) Except as stated above, the Commission shall follow the procedure for suspension of a medical cannabis card only upon holding a hearing as set forth in Chapter 1 of these Rules. The suspension shall remain in effect, unless removed by the Commission, until the Commission's final adjudication order becomes effective, except that if the Commission does not issue its final adjudication order within ninety days after the hearing, the suspension shall thereafter be void.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, \$\$20-2A-22, as amended. History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.13 <u>Confidential Information</u>.

Any document that is a patient record or that contains information that is required to be kept confidential according to any state or federal law, for purposes of the administrative hearing only, may be provided to a representative of record or to a witness in any proceedings before the Commission or any appeal or other administrative or judicial proceedings arising therefrom. Confidential information may also be provided in response to a judicial order or a subpoena by any party issued from a court of competent jurisdiction. Except as stated herein, confidential information shall not be disseminated to any other person unless the confidential information is redacted.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, \$\$20-2A-22, as amended. History: New Rule: Published August 31, 2022; effective October 15, 2022.