Recommendations of the Tennessee Medical Cannabis Commission

2022 Report to the 112th Tennessee General Assembly

Tennessee Medical Cannabis Commission

January 4, 2022

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I. Executive Summary

On May 5, 2021, the Tennessee General Assembly passed Senate Bill 118 / House Bill 490 of the 112th General Assembly which became Public Chapter 577. Governor Lee signed Public Chapter 577 on May 27, 2021 thereby making Public Chapter 577 the public policy of this State, codified in Title 68 along with Title 4 and Title 39. This legislation created the Tennessee Medical Cannabis Commission ("Commission").

The Commission "shall prioritize the recommendations for the creation of a patient registration process or program that includes patients with a qualifying medical disease or condition recommended by the commission" for purposes of facilitating patient reciprocity with other states.[1] The Commission shall report its findings to the General Assembly by January 1 of each calendar year, beginning in January of 2022, and include proposed legislation in its findings.[2] This report contains recommendations and proposed legislation in the form of recommended text. The recommended text prioritized a patient registry for qualified patients along with protections for qualified patients and designated caregivers.

The Commission recommends a system whereby a qualified patient (and / or caregiver) obtains a qualified patient (and / or designated caregiver) identification card issued by the Commission. A qualified patient or designated caregiver identification card coupled with an acceptable form and amount (of medical cannabis) shall be protected from a variety of actions (e.g. civil, criminal, employment, parental visitation, etcetera), in accordance with the provisions in the recommended text. There is not a recommendation in this report for a supply-based system.

No other state's medical cannabis program offers an identification card without a supply-based framework to use the card in the state from which it was issued. This is a first-of-its-kind initiative. A few states allow for possession of low-dose Delta-9-Tetrahydrocannabinol ("THC"). The approach recommended (by the Commission) is entirely dependent upon other states continuing to allow non-residents / non-citizens access to those states' supply chain. Reliance on other states is a limitation.

The Commission is very thankful for the opportunity it has been given. The complexities and nuances of this subject – medical cannabis – present a host of challenges to solve. These challenges require testimony from experts in medicine, pharmacology, patient advocacy, and law enforcement for matters relevant to the patient. As the Commission broadens its scope, the subject matter experts necessary to form proper opinion also increase in volume. The Commission heard from several people. There are still many, many more people to hear from. The Commission pushed quickly to produce these recommendations. The Commission now hopes to explore matters in significant detail while also revising matters within this report.

The recommended text, in section III of this document, is a verbatim representation of suggested statutory language. Section IV contains commentary about selected provisions of the recommended text. The commentary is a result of dialogue conducted by the Commission on various topics. The topics appear in the order of the recommended text.

II. The Commission

Background

The Commission consists of nine (9) members – three (3) appointed by the Speaker of the Senate , three (3) appointed by the Speaker of the House of Representatives, and three (3) appointed by the governor. There is an attendance provision and a term limit for each appointment as outlined in T.C.A. § 68-7-103. Between August and December of 2021, all nine positions were appointed. Membership is as follows:

Senate:	1.) Russell Johnson – District Attorney General, 9th Judicial District
	2.) Dr. Steve Dickerson – Medical Doctor, anesthesiologist
	3.) Dr. Ray Marcrom – Pharmacist, owner of Marcrom's Pharmacy
House of Representatives:	1.) Dr. Barry Walton – Pharmacist, owner of Mac's Medicine Mart (pharmacy)
	2.) Dr. Ana Lisa Carr – Medical Doctor, family practice
	3.) David Griswold – Chief of Police, Nashville International Airport
Governor:	1.) Paul Thomas – Sheriff, Gibson County Tennessee
	2.) Cari Parker – Former vice president, Eastman Chemical Company
	3.) Curtis Harrington – Attorney, Belcher Sykes Harrington, PLLC

The Commission met six (6) times between October 1, 2021 and December 17, 2021. Meetings occurred on the following dates:

- October 1, 2021 (quorum not present)
- October 15, 2021
- November 5, 2021
- November 19, 2021
- December 10, 2021
- December 17, 2021

At its meeting on October 15, 2021, the Commission elected Dr. Dickerson to serve as its chairperson and District Attorney General Johnson to serve as vice chairperson. The Commission received administrative support from the Tennessee Department of Health via Ms. Kimberly Wallace, regulatory board administrative director and Mr. Matthew (Matt) Gibbs, deputy general counsel.

The purpose of the Commission is to "serve as a resource for the study of federal and state laws regarding medical cannabis and the preparation of legislation to establish an effective, patient-focused medical cannabis program in this state upon the rescheduling or descheduling of marijuana from Schedule I of the

federal Controlled Substances Act[.]"[3] The Commission is not charged with oversight of an operational program for cultivation, processing, shipping, or distribution of medical cannabis to patients in this state until such time as a change in status under federal law.

The Commission shall study several concepts as part of its duty. These concepts center around "how best to establish an effective, patient-focused medical cannabis program… including provisions that create an independent and financially self-sufficient commission, to be governed by its appointed members[.]"[4]

The Commission shall address the appointment of its executive director during the 2022 calendar year. Given the timeline of this report, which regards the concepts of approved states and patient registration applicable to medical cannabis, the Commission wished to prioritize this report first.

Guest speakers

The Commission routinely heard from patient advocates, representatives of law enforcement, subject matter experts and members of the public during its meetings. This is a brief overview of each presenter's remarks to the Commission.

a. Holly and T.J. Ramsey – patient advocates

Ms. Ramsey, mother of T.J. Ramsey, spoke to the Commission on October 15, 2021. Physicians diagnosed T.J. Ramsey, a minor child, with a rare neurological disorder, cerebral palsy, and epilepsy. As a small child, T.J. Ramsey received traditional pharmaceuticals for his conditions. After several failed interventions, T.J. Ramsey began using low-dose medical cannabis. He experiences a significant increase in his quality of life through the use of medical cannabis. Ms. Ramsey asked the Commission to consider a program which allowed close, safe access to medical cannabis.

b. Will Tarleton – concerned citizen (hemp cultivation)

Mr. Tarleton spoke to the Commission in his individual capacity. Mr. Tarleton asked the Commission to consider how its actions will impact businesses, farmers, industrial processes, law enforcement, public safety, civil possession, taxation, incarceration rates, along with other issues.

c. Elizabeth Stroecker, Esq. – Tennessee Department of Safety

The Commission welcomed Ms. Stroecker on November 5, 2021 and December 10, 2021. Ms. Stroecker spoke about identification mechanisms and real time reporting through the lens of law enforcement along with drug recognition. The purpose of coded classifications on a driver's license is to minimize the opportunity to be targeted because of a medical condition. Real time reporting must be considered by the Commission for both information into and out of the patient registry.

d. Kent Morrell – Safe Access Tennessee

Mr. Morrell addressed the Commission on November 19, 2021 as a patient advocate. A traffic accident in 2000 led Mr. Morrell to be a high-dose pain management patient. After a number of interventions, Mr.

Morrell tried medical cannabis. Mr. Morrell believes medical cannabis saved his life and has contributed to an improved quality of life.

e. David Hairston – Safe Access Tennessee

Mr. Hairston spoke to the Commission on November 19, 2021 as a patient advocate and representative of Safe Access Tennessee. Safe Access Tennessee is a nonprofit medical cannabis advocacy organization consisting of disabled patients and their family caregivers. Safe Access Tennessee only advocates for medicinal use of cannabis.

f. Lt. Dwayne Standford – Tennessee Highway Patrol, drug recognition expert

Lieutenant Dwayne Standford serves as a drug recognition expert in addition to other assigned duties with the Tennessee Highway Patrol. Lt. Standford gave remarks to the Commission on December 10, 2021. Lt. Standford noted the need to educate and train both the patients and law enforcement personnel should legislation pass relative to medical cannabis. Lt. Standford provided specific examples of traffic incidents involving cannabis including the dangers of impairment while operating a motor vehicle. The Commission queried Lt. Standford on a variety of matters including criminal fraud and patient registry identification.

g. Mike Lyttle – Tennessee Bureau of Investigation, lab director

The Commission heard from Director Lyttle on December 10, 2021. Director Lyttle spoke about lab-based statistics, testing methodologies, and toxicology relevant to cannabis. Nuances between lab-based tests for alcohol and cannabis were discussed. Director Lyttle described eccentricities involving cannabis relevant to the work of the crime lab.

h. Patrick Powell, Esq. - Tennessee Bureau of Investigation

Mr. Powell addressed the Commission on December 10, 2021. Mr. Powell noted concerns relative to reciprocity, illicit activity, and matters relating to packaging and patient registry identification through the lens of law enforcement. Should legislation pass relevant to medical cannabis, there will be a need to staff, educate and train responsible persons in an effort to combat nefarious actors.

Review of other jurisdictions

States with a reciprocity component to their medical cannabis program,[5] but without an adult use program, considered by the Commission include[6]:

a. Arkansas

A constitutional amendment in 2016 authorized medical cannabis use in the state of Arkansas. The Arkansas Department of Health administers the medical cannabis program. Under this program, a qualified patient, who may be a citizen or nonresident, may visit an Arkansas dispensary and purchase dried leaves, flowers, oils, vapors, waxes, and other portions of the marijuana plant assuming the presence of a qualifying condition.[7] The possession limit in Arkansas is two and one-half ounces (2 ½ oz.) of usable

marijuana.[8] From July 1, 2019 through June 30, 2020, a total of 47,002 patients submitted applications for a Medical Marijuana Registry ID Card. Of those, 43,630 applications were approved. There were 3,372 applications pending due to incomplete information. The most prevalent qualifying medical condition among Medical Marijuana Registry Identification Card recipients was intractable pain unresponsive to medicines, treatment, or surgery for more than six (6) months.[9]

b. Florida

A constitutional amendment in 2016 authorized medical cannabis use in the state of Florida. The Florida Department of Health, Office of Medical Marijuana Use administers the medical cannabis program. As of October 29, 2021, there were 631,660 qualified patients in the program.[10] Under the vertically integrated approach in Florida, qualified patients, if recommended by a Florida physician, may purchase no more than two and one-half ounces (2 ½ oz.) every 35 days or four ounces (4 oz.) every 70 days of smokable flower.[11] Florida law requires medical marijuana treatment centers to offer at least one low-THC product.[12] Florida's program allows for patients to be enrolled through "seasonal resident" status.[13]

c. Missouri

A 2018 ballot measure passed in the state of Missouri which authorized a medical cannabis program. The Missouri Department of Health and Senior Services administers the program. Qualified patients may purchase no more than four ounces (4 oz.) of dried flower in a 30-day period. Production of the respective equivalent identification card or authorization issued by another state or political subdivision of another state shall also meet the requirements of Missouri law.[14] In the 2020 Annual Report, the Missouri Department of Health and Senior Services reports 56,448 new patient licenses were issued and 12,062 patient licenses were renewed.[15]

d. Ohio

A 2016 legislative enactment created the Ohio Medical Marijuana Program. Qualified patients may purchase forms of medical cannabis which do not require smoking or combusting but may be vaporized.[16] The Ohio Medical Marijuana Program, comprised of the State of Ohio, Ohio Board of Pharmacy, the State Medical Board of Ohio, and in conjunction with the Department of Commerce (of Ohio), administers the program. The Ohio Board of Pharmacy shall attempt to enter into a reciprocity agreement with any other state under which a medical marijuana registry identification card or equivalent authorization that is issued by the other state is recognized in the state of Ohio.[17] The Ohio Board of Pharmacy utilizes a days-supply dispensation reference to calculate purchase limits which is based upon THC potency.[18]

e. Oklahoma

A 2018 referendum initiative passed in the state of Oklahoma which created its medical cannabis program. The Oklahoma Medical Marijuana Authority administers the program under the Oklahoma State Department of Health. "A medical marijuana license shall be recommended according to the accepted standards a reasonable and prudent physician would follow when recommending or approving any medication" - there are no qualifying conditions to enter Oklahoma's medical cannabis program.[19] Oklahoma sees significant participation in its medical cannabis program.[20]

III. Recommended Text

I.) Definitions

1. "Acceptable form of medical cannabis" means oils, tinctures, patches, edibles, vapors, waxes and other portions of the cannabis plant and any mixture or preparation thereof that is concealed in its manufacturer's original packaging and labeling from an approved state and which meets any and all labeling and other specifications as determined by the Commission in rule, excluding, but not limited to, dried leaves, flowers, seeds, roots, stems, stalks and fan leaves.

2. "Designated caregiver" means a resident of this state who has agreed to assist with a qualified patient's medical use of cannabis, has a designated caregiver identification card, and meets the requirements of section six (6).

3. "Designated caregiver identification card" means a document issued by the Commission that identifies a person as a designated caregiver.

4. "Commission" means the Tennessee Medical Cannabis Commission.

5. "Good faith belief" means reasonable reliance on a fact, or that which is held out to be factual, without intent to deceive or be deceived and without reckless or malicious disregard for the truth.

    a) "Good faith belief" does not include a belief formed with gross negligence.

    b) "Good faith belief" may be based on any of the following:

        (1) Observed conduct, behavior, or appearance;

        (2) Information reported by a person believed to be reliable, including without limitation a report by a person who witnessed the use or possession of medical cannabis or medical cannabis paraphernalia by an applicant or employee in the workplace;

        (3) Written, electronic, or verbal statements from the employee or other persons;

        (4) Lawful video surveillance;

        (5) A record of government agencies, law enforcement agencies, or courts;

        (6) A positive test result for marijuana / THC;

(7) A warning label, usage standard, or other printed material that accompany instructions for medical cannabis;

(8) Information from a physician, medical review officer, or a dispensary;

(9) Information from reputable reference sources in print or on the internet;

(10) Other information reasonably believed to be reliable or accurate; or

(11) Any combination of the items listed in subdivisions (5)(b)(1)-(10) of this section;

6. "Manufacturer's original packaging and labeling" means packaging and labeling which is compliant with the laws of the approved state, which includes seed-to-sale tracking, and the manufacturer, cultivator, processor, or distributor who packaged and/or labeled the acceptable form of medical cannabis is licensed by the appropriate oversight body in the approved state where the product is purchased.

7. "Marijuana" means the same as defined in T.C.A. § 39-17-402(16).

8. "Possession limit" means the limit of an acceptable form of medical cannabis a qualified patient or designated caregiver may possess at any one time.

9. "Qualified medical condition" means any of the following:

a) Alzheimer's disease;

b) Amyotrophic lateral sclerosis (ALS);

c) Cancer, when such disease is diagnosed as end stage or the treatment produces related wasting illness, recalcitrant nausea and vomiting, or pain;

d) Inflammatory bowel disease, including Crohn's disease and ulcerative colitis;

e) Epilepsy or seizures;

f) Multiple sclerosis;

g) Parkinson's disease;

h) Human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS);

j) Sickle cell disease; or

i) Any other disease or condition recommended by the Medical Cannabis Commission pursuant to rules promulgated by the Commission.

10. "Qualified patient" means:

a) A resident of this state;

b) A patient that has been diagnosed by a qualified physician as having a qualifying medical condition; and

c) A patient who has registered with the Commission and received a qualified patient identification card.

11. "Qualified patient identification card" means a document issued by the Commission that identifies a person as a qualified patient.

12. "Qualified physician" means a person who holds an active, valid, and unrestricted license as a physician under Title 63, Chapter 6 or as an osteopathic physician under Title 63, Chapter 9.

13. "Approved state" means the states of Arkansas, Delaware, Missouri, Ohio, Rhode Island, and Utah. The Commission may approve other states as determined by the Commission. In adopting other states for approval, the Commission shall consider whether other states allow participation in a medical cannabis program by citizens of this state. Other considerations include provisions for seed-to-sale tracking, packaging, labeling, and a licensing structure.

14. "Written certification" means a document created by a physician stating that in the physician's professional opinion, after having completed an assessment of the qualified patient's medical history, medication history and a face-to-face assessment of the patient's current medical condition, made in the course of a physician-patient relationship, the qualified patient has a qualified medical condition.

a) A physician shall not issue a written certification to a patient based on an assessment performed through telemedicine.

b) A written certification is not a medical prescription.

II. Protections

1. A qualified patient or designated caregiver in actual possession of a qualified patient or designated caregiver identification card shall not be subject to arrest, prosecution, or penalty in any manner or denied any right or privilege, including without limitation a civil penalty or disciplinary action by a business, occupational, or professional licensing board or bureau, for the medical use of cannabis

in accordance with this Chapter if the qualified patient or designated caregiver possesses an amount less than or equal to:

a) ____ grams of concentrated product; or

b) ____ milligrams of infused products

2. A qualified patient or designated caregiver is presumed to be lawfully engaged in the medical use of cannabis in accordance with this chapter if the qualified patient or designated caregiver is in actual possession of a qualified patient or designated caregiver identification card and possesses an acceptable form of medical cannabis that does not exceed the amount allowed under this chapter.

a) The presumption made in subsection two (2) may be rebutted by evidence the medical cannabis exceeded the allowable amount.

b) An acceptable form of medical cannabis shall be the only forms allowed for possession.

3. A school or landlord shall not refuse to enroll, refuse to lease to, or otherwise penalize an individual solely for his or her status as a qualified patient or designated caregiver unless doing so would put the school or landlord in violation of federal law or regulations.

4. For the purposes of medical care, a qualified patient's authorized use of medical cannabis in accordance with this amendment is considered the equivalent of the authorized use of any other medication used at the direction of a physician and does not constitute the use of an illicit substance.

5. An employer shall not discriminate against an applicant or employee in hiring, termination, or any term or condition of employment, or otherwise penalize an applicant or employee, based upon the applicant's or employee's past or present status as a qualified patient or designated caregiver.

a) A cause of action shall not be established against an employer based upon, and an employer is not prohibited from, any of the following actions:

(1) Establishing and implementing a substance abuse or drug-free workplace policy that may include a drug testing program that complies with state or federal law and taking action with respect to an applicant or employee under the policy;

(2) Acting on the employer's good faith belief that a qualified patient:

(A) Possessed, ingested, or otherwise engaged in the use of medical cannabis while on the premises of the employer or during the hours of employment; or

(B) Was under the influence of medical cannabis while on the premises of the employer or during the hours of employment, provided that a positive test result for marijuana / THC cannot provide the sole basis for the employer's good faith belief; or

(3) Acting to exclude a qualified patient from being employed in or performing a safety sensitive position based on the employer's good faith belief that the qualified patient was engaged in the current use of medical cannabis.

b) For reasons other than an applicant's or employee's past or present status as a qualified patient or designated caregiver, the authorized or protected actions of an employer under this subdivision include without limitation:

(1) Implementing, monitoring, or taking measures to assess, supervise, or control the job performance of an employee;

(2) Reassigning an employee to a different position or job duties;

(3) Placing an employee on paid or unpaid leave;

(4) Suspending or terminating an employee;

(5) Requiring an employee to successfully complete a substance abuse program before returning to work;

(6) Refusing to hire an applicant for reasons other than being a qualified patient; or

(7) Any combination of the actions listed in subsection (b)(1) through (6).

c) Damages established for an employment discrimination claim based on an applicant's or employee's past or present status as a qualified patient or designated caregiver in violation of this chapter shall be limited to the damages available for an employment discrimination claim under Tennessee law.

(1) Liability for back pay shall not accrue from a date more than two (2) years prior to the filing of an action.

(2) Damages under this subdivision shall not duplicate or increase an award for damages over the statutory limit allowed by state law or federal law existing on January 1, 2022, whichever is lower.

d) An action based on employment discrimination in violation of this subdivision shall be brought within one (1) year of the occurrence of the alleged discrimination.

e) An individual employee, agent of the employer, or employee of the agent of the employer is not liable for any violation of this subdivision that the employer is found to have committed.

f) This chapter does not waive the sovereign immunity of the State of Tennessee.

6. A person otherwise entitled to custody of, or visitation or parenting time with, a minor shall not be denied custody, visitation, or parenting time solely for conduct allowed under this chapter, nor shall there be:

a) A finding of abuse solely for conduct allowed under this chapter; or

b) A presumption of neglect or child endangerment for conduct allowed under this chapter.

7. Any acceptable form of medical cannabis under possession limits, medical cannabis paraphernalia, licit property, or interest in licit property, that is possessed, owned, or used exclusively in connection with the medical use of cannabis as allowed under this chapter, or property incidental to such use, shall not be seized or forfeited.

a) Forms not acceptable or amounts in excess of possession limits may be seized and forfeited.

b) Medical cannabis not contained in the manufacturer's original packaging and labeling may be seized and forfeited.

8. A person shall not be subject to arrest, prosecution, or penalty in any manner or denied any right or privilege, including without limitation a civil penalty or disciplinary action by a business, occupational, or professional licensing board or bureau, simply for being in the presence or vicinity of the medical use of cannabis as allowed under this Chapter or for directly assisting a qualified patient with the medical use of cannabis.

9. A physician shall not be subject to arrest, prosecution, or penalty in any manner or denied any right or privilege, including without limitation a civil penalty or disciplinary action by the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examiners or by any other business, occupational, or professional licensing board or bureau, solely for providing a written certification.

a) This section does not prevent the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examiners from sanctioning a physician for failing to properly evaluate a patient's medical condition or for otherwise violating the applicable physician-patient standard of care or the corresponding practice acts under Title 63.

b) This section does not require a physician to issue a written certification.

10. School personnel may possess medical cannabis under the provisions of § 49-50-1601 through 1604 when obtained for medical use pursuant to this section by a student who is a qualified patient.

11. This section does not prohibit the medical use of cannabis or a designated caregiver assisting with the medical use of cannabis in a Tennessee-licensed nursing home facility, hospice facility, or an assisted living facility, if the medical use of cannabis is permitted under federal law.

III. Written certification

1. A qualified patient shall obtain a new written certification at least annually. In every application for which a written certification is required, the written certification must be less than thirty (30) days old at the time the application is submitted.

2. A written certification shall contain the following information:

a) The physician's name, as it appears in the records of the Board of Medical Examiners or Board of Osteopathic Examination;

b) The physician's licensee number including his/her United States Drug Enforcement Agency number;

c) The physician's business address, telephone number, and email address;

d) The qualified patient's name, address, and date of birth.;

e) The qualified patient's qualified medical condition;

f) Statements confirming the following:

(1) In the case of a non-emancipated qualified patient under the age of eighteen (18), before certifying the qualified patient, the physician received the written consent of a parent or legal guardian who asserts he or she will serve as a primary designated caregiver for the qualified patient;

(2) The physician met with and examined the qualified patient, reviewed the qualified patient's medical records or medical history, reviewed the qualified patient's current medications and allergies to medications, discussed the qualified patient's current symptoms, and created a medical record for the qualified patient regarding the meeting;

(A) This review includes accessing the Controlled Substance Monitoring Database and the Patient Registry to confirm the patient does not have an active physician certification from another qualified physician

(3) In the opinion of the physician, the qualified patient suffers from the qualified condition; and

g) The signature of the physician and date on which the physician signed.

3. The qualified physician shall register within the Patient Registry as the issuer of the written certification for the named qualified patient in an electronic manner determined by the Commission, and shall:

a) Enter into the Patient Registry the contents of the physician's written certification, including the patient's qualified condition and a designated caregiver if the qualified patient is a minor.

b) Update the Patient Registry within seven (7) days after any change is made to the original physician certification to reflect such change.

c) Deactivate the written certification within the Patient Registry of the qualified patient and the patient's designated caregiver when the qualified physician determines the patient no longer meets the criteria of a qualified patient.

4. A qualifying physician shall obtain the voluntary and informed written consent of the patient each time the qualified physician issues a written certification for the patient, which shall be maintained in the patient's medical record. The patient, or the patient's parent or legal guardian if the patient is a minor, must sign the informed consent acknowledging that the qualified physician has sufficiently explained its content. The qualified physician must use a standardized informed consent form adopted by the Commission, which must include, at a minimum, information related to:

a) The Federal Government's classification of medical cannabis in the federal Controlled Substance Act of 1970;

b) The approval and oversight status of medical cannabis by the Food and Drug Administration;

c) The potential for addiction and resources available for addiction;

d) The potential effect that medical 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 a person to be alert or respond quickly;

e) The potential side effects of medical cannabis use, including the negative health risks associated with smoking medical cannabis; and

f) Possible limitations placed on Tennessee citizens who seek to obtain medical cannabis in another state

IV. Patient Registry

1. The Commission shall create and maintain a secure, electronic, and online Patient Registry for qualified physicians, qualified patients, and designated caregivers as provided under this section. The Patient Registry shall be accessible to law enforcement agencies and qualified physicians to verify the authorization of a qualified patient or a designated caregiver to possess medical cannabis. The Patient Registry must also be accessible to practitioners licensed to prescribe prescription drugs to ensure proper care for patients before medications that may interact with the medical use of cannabis are prescribed. The Patient Registry must prevent an active registration of a qualified patient by multiple physicians.

2. The Commission confirms qualified patients within the Patient Registry.

3. The Commission shall determine whether an individual is a resident of this state for the purpose of registration of qualified patients and designated caregivers in the Patient Registry. To prove residency, a qualified patient shall submit at least two of the following forms of proof:

a) An adult resident shall provide the Commission with a copy of his or her valid Tennessee driver license or identification card issued under the laws of this state.

b) A deed, mortgage, monthly mortgage statement, mortgage payment booklet or residential rental or lease agreement.

c) A utility hookup or work order dated within sixty (60) days before registration in the medical use registry.

d) A utility bill, not more than two (2) months old.

e) Mail from a financial institution, including checking, savings, or investment account statements, not more than two (2) months old.

f) Mail from a federal, state, county, or municipal government agency, not more than two (2) months old.

g) Any other documentation that provides proof of residential address as determined by Commission rule.

h) A minor must provide the Commission with a certified copy of a birth certificate or a current record of registration from a Tennessee K-12 school and must have a parent or legal guardian who meets the requirements of this section.

4. The Commission may suspend or revoke the registration of a qualified patient or designated caregiver if the qualified patient or designated caregiver:

a) Provides misleading, incorrect, false, or fraudulent information to the Commission;

b) Possesses a form or amount other than the acceptable form of medical cannabis or in an amount that exceeds possession limits;

c) Falsifies, alters, or otherwise modifies a qualified patient identification card;

d) Fails to timely notify the Commission of any changes to his or her qualified patient status; or

e) Violates the requirements of this section or any rule adopted under this section.

5. The Commission shall revoke the registration of a qualified patient, and the patient's designated caregiver, upon notification by the qualified physician that the patient no longer meets the criteria of a qualified patient.

6. Upon request and for purposes of verifying whether a particular individual is lawfully in possession of a qualified patient or designated caregiver identification card or lawfully in possession of a particular amount of medical cannabis, state and local law enforcement personnel shall have access to patient and designated caregiver information such as names, addresses, and dates of birth, but not information about the patient's qualified medical condition.

V. Qualified patient and designated caregiver identification card

1. The Commission shall issue qualified patient or designated caregiver identification cards for qualified patients and designated caregivers who are residents of this state and who have submitted application and fee to the Commission following registration by a qualified physician. A qualified patient or designated caregiver identification card shall be renewed annually through the application process. The qualified patient or designated caregiver identification cards must be resistant to counterfeiting and tampering and must include, at a minimum, the following:

a) The name, address, and month and year of birth of the qualified patient or designated caregiver.

b) A full-face, passport-type, color photograph of the qualified patient or designated caregiver taken within the 90 days immediately preceding registration or the Tennessee driver license or Tennessee identification card photograph of the qualified patient or designated caregiver obtained directly from the Department of Safety and Homeland Security.

c) Identification as a qualified patient or a designated caregiver.

d) The unique numeric identifier used for the qualified patient in the Patient Registry.

e) For a designated caregiver, the name and unique numeric identifier of the designated caregiver and the qualified patient or patients that the designated caregiver is assisting.

f) The expiration date of the identification card.

2. The qualified patient shall complete registration within the Patient Registry in a manner determined by the Commission in rule, by:

a) Submitting a completed application within 30 days of issuance of the Written Certification; and

b) Paying the nonrefundable application fee.

3. The Commission must receive written consent from a qualified patient's parent or legal guardian before it may issue an identification card to a qualified patient who is a minor.

4. Applications for qualified patient or designated caregiver identification cards must be submitted on a form prescribed by the Commission. The Commission may charge a reasonable fee associated with the issuance, replacement, and renewal of identification cards. The Commission may contract with a third-party vendor to issue identification cards. The vendor selected by the Commission must have experience performing similar functions for other state agencies.

5. A qualified patient or designated caregiver shall return his or her identification card to the Commission within 5 business days after revocation.

6. All qualified patients and designated caregivers are required to have a valid qualified patient or designated caregiver identification card on their person to possess an acceptable form of medical cannabis and shall present the qualified patient or designated caregiver card to law enforcement personnel upon request.

7. To apply for a qualified patient identification card, a person must:

a) Be a Tennessee resident

b) Be a qualified patient who has been added to the Patient Registry, and;

c) Submit an application available from the Commission less than 30 days after being added or renewed within the Patient Registry.

8. To apply for a designated caregiver identification card, a person must submit an application to the Commission.

9. In order for a minor patient to receive a qualified patient identification card, the minor patient must reside in Tennessee and have a designated caregiver designated in his or her application and in the online Patient Registry.

10. Each person who applies for a qualified patient or designated caregiver identification card shall pay a $50 application fee in a form as determined by the Commission. The card shall expire one (1) year after the date of issuance.

11. A person who applies for a qualified patient or designated caregiver identification card shall have sixty (60) days from the date the Commission provides notice that the application is incomplete to make corrections, provide additional information or resubmit the application.

12. To maintain an active qualified patient or designated caregiver identification card, a patient and/or designated caregiver must annually submit an application on a form issued by the Commission, along with the non-refundable application fee and any required accompanying documents to the Commission forty-five (45) days prior to the card expiration date.

13. When there has been a change in the patient's name, address, or designated caregiver, that patient must notify the Commission within ten (10) days by submitting a completed change form issued by the Commission, along with a $15 replacement fee in the form as determined by the Commission. A patient who has not designated a designated caregiver at the time of application to the Commission may do so in writing at any time during the effective period of the qualified patient’s identification card.

14. A patient who no longer has a qualified medical condition shall return his or her registry identification card to the Commission within ten (10) days of receiving such information by his or her physician along with a form issued by the Commission.

15. Requests to replace a lost or stolen card will require the cardholder to submit a form issued by the Commission, along with a copy of his or her Tennessee driver's license or identification card and a $15 replacement fee.

16. The Commission may revoke a qualified patient or designated caregiver identification card for any of the following:

a) The patient or designated caregiver makes material misrepresentations in his or her application;

b) The patient uses his or her card to obtain medical cannabis for another individual;

c) The designated caregiver uses his or her card to obtain medical cannabis for an individual who has not designated them as their designated caregiver or who is not a qualified patient;

d) The patient is no longer a qualified patient.

e) Any other violation of this chapter or reason adopted as a rule promulgated by the Commission.

17. The Commission shall review the information contained in an application for a qualified patient or designated caregiver identification card within forty-five (45) days of receiving all the information required for the application, including the written certification from the physician. The application shall be granted and a qualified patient or designated caregiver identification card shall be issued if it is not reviewed after forty-five (45) days of receiving all required information.

a) The Commission may authorize its designee to conduct a review of the qualifications of an applicant for a qualified patient or designated caregiver identification card and to make an initial determination as to whether the applicant has met all the requirements for issuance of a qualified patient or designated caregiver identification card. If the designee determines the applicant has met all the requirements for a qualified patient or designated caregiver identification card, the designee has the authority to issue to such applicant a temporary qualified patient or designated caregiver identification card. In no event shall the temporary qualified patient or designated caregiver identification card issued pursuant to an initial determination made by a Commission designee be effective for longer than a 45-day period measured from the date of issuance.

b) If temporary qualified patient or designated caregiver identification card, pursuant to subsection (a), is issued to an applicant and if the subsequent decision of the Commission is to deny the application based upon a determination that the applicant has not complied with all the requirements for a qualified patient or designated caregiver identification card, then the initial approval from that point forward shall immediately become null and void, and the applicant shall be notified immediately. In this event, the doctrine of estoppel shall not apply against the state based upon its issuance of temporary authorization and its subsequent denial of a qualified patient or designated caregiver identification card.

18. The Commission shall deny an application if:

a) The applicant had a previous registry identification card revoked in this state or any other jurisdiction where medical cannabis use is allowed;

b) The written certification was not made in the context of a physician-patient relationship;

c) The written certification was fraudulently obtained; or

d) The application or written certification was falsified in any way.

19. All documentation submitted by qualified patients or designated caregivers, including but not limited to applications and written certifications, shall remain confidential and not subject to subpoena or Public Records Request.

a) This section does not apply to access designated for law enforcement agencies.

VI. Designated caregivers

1. A qualified patient shall designate a designated caregiver, if one is desired, in the patient's application. A minor patient shall designate a designated caregiver.

2. A designated caregiver shall complete a form issued by the Commission, submit the form to the Commission, and pay a fee of $50 before the Commission issues a designated caregiver identification card.

3. The Commission must register an individual as a designated caregiver on Patient Registry and issue a designated caregiver identification card if an individual designated by a qualified patient meets all of the requirements of this subsection and Commission rule.

4. A designated caregiver must:

a) Not be a qualified physician, unless the qualified physician is the parent or legal guardian of a minor child.

b) Be 21 years of age or older and a resident of this state.

c) Agree in writing to assist with the qualified patient's medical use of cannabis.

d) Be registered in the Patient Registry as a designated caregiver for no more than one qualified patient, except as provided in this subsection.

e) Successfully complete a designated caregiver certification course developed and administered by the Commission or its designee and approved by the Commission, which must be renewed biennially.

f) Submit the results of a criminal background check pursuant to § 63-1-116, unless the designated caregiver is the parent(s) of the patient.

5. A qualified patient may designate no more than one designated caregiver to assist with the qualified patient's medical use of cannabis, unless:

a) The qualified patient is a minor and the designated caregivers are parents or legal guardians of the qualified patient;

b) The qualified patient is an adult who has an intellectual or developmental disability that prevents the patient from being able to protect or care for himself or herself without assistance or supervision and the designated caregivers are the parents or legal guardians of the qualified patient; or

c) The qualified patient is admitted to a hospice program.

6. A designated caregiver may be registered in the Patient Registry as a designated caregiver for no more than one qualified patient, unless:

a) The designated caregiver is a parent or legal guardian of more than one minor who is a qualified patient;

b) The designated caregiver is a parent or legal guardian of more than one adult who is a qualified patient and who has an intellectual or developmental disability that prevents the patient from being able to protect or care for himself or herself without assistance or supervision; or

c) All qualified patients the designated caregiver has agreed to assist are admitted to a hospice program and have requested the assistance of that designated caregiver with the medical use of cannabis; the designated caregiver is an employee of the hospice; and the designated caregiver provides personal care or other services directly to clients of the hospice in the scope of that employment.

7. A designated caregiver may not receive compensation, other than actual expenses incurred, for any services provided to the qualified patient. This prohibition on compensation shall not apply to designated caregivers serving as a designated caregiver under this Chapter in conjunction with the designated caregiver's primary employment under state or federal law.

8. A designated caregiver identification card shall be on the designated caregiver's person when in possession of medical cannabis and the designated caregiver must present his or her designated caregiver identification card upon the request of a law enforcement officer.

9. A designated caregiver identification card shall be valid from the date of issuance and expire one year later, on the last day of the month it was issued.

10. The Commission may adopt rules to implement this subsection.

VII. Limitations

1. This section does not permit a person to:

    a) Undertake any task under the influence of medical cannabis when doing so would constitute negligence or professional malpractice;

    b) Operate, navigate, or be in actual physical control of a motor vehicle, aircraft, motorized watercraft, or any other vehicle drawn by power other than muscle power while under the influence of medical cannabis. Impairment shall be determined by a totality of the circumstances;

2. This amendment does not require:

    a) A government medical assistance program or private health insurer to reimburse a person for costs associated with the medical use of cannabis unless federal law requires reimbursement;

    b) An employer to accommodate the ingestion of medical cannabis in a workplace or an employee working while under the influence of medical cannabis;

    c) An individual or establishment in lawful possession of property to allow a guest, client, customer, or other visitor to use medical cannabis on or in that property;

    d) An individual or establishment in lawful possession of property to admit a guest, client, customer, or other visitor who is impaired as a result of his or her medical use of cannabis; or

    e) A public school to permit a qualified patient who is a student to be present on school grounds, to attend a school event, or to participate in extracurricular activities in violation of the public school's student discipline policies when a school office has a good faith belief that the behavior of the qualified patient is impaired.

3. This subsection does not exempt a person from prosecution for a criminal offense related to impairment or intoxication resulting from the medical use of cannabis or relieve a person from any requirement under law to submit to a breath, blood, urine, or other test to detect the presence of a controlled substance.

4. This section does not limit the ability of an employer to establish, continue, or enforce a drug-free workplace program or policy.

5. This section does not require an employer to accommodate the medical use of cannabis in any workplace or any employee working while under the influence of medical cannabis.

6. This section does not create a cause of action against an employer for wrongful discharge or discrimination.

VIII. Penalties

1. A qualified physician commits a [Class A misdemeanor], if the qualified physician issues a written certification for a patient without a reasonable belief that the patient is suffering from a qualified medical condition.

2. A person who fraudulently represents that he or she has a qualified medical condition to a qualified physician for the purpose of being issued a written certification commits a [Class A misdemeanor].

3. A qualified patient or designated caregiver who possesses medical cannabis in an unauthorized form or in an amount beyond possession limits or not contained in the manufacturer's original packaging and labeling is subject to the penalties of Title 39, regardless of Patient Registry status or the validity of a qualified patient or designated caregiver identification card.

4. A qualified patient or designated caregiver in possession of medical cannabis who fails or refuses to present his or her qualified patient or designated caregiver identification card upon the request of a law enforcement officer commits a Class C misdemeanor, unless it can be determined through the Patient Registry that the person is authorized to be in possession of that medical cannabis.

5. A designated caregiver who violates any of the applicable provisions of this section or applicable Commission rules, for the first or second offense, commits a Class C misdemeanor and, for a third or subsequent offense, commits a Class A misdemeanor. New offenses do not preclude or prohibit other violations under Title 39.

6. A physician who issues a written certification shall not have an employment or direct or indirect ownership of an equity interest, including direct ownership of stock or shares from a business engaged in the cultivation, processing, shipping, or distribution of cannabis for medical use and shall be referred to the proper license board for disciplinary action under the applicable practice act for issuing such written certification while in possession of employment or direct or indirect ownership of an equity interest; and

7. Any person who possesses or manufactures a blank, forged, stolen, fictitious, fraudulent, counterfeit, or otherwise unlawfully issued qualified patient or designated caregiver identification card commits a [Class D felony].

IX. Rulemaking Authority

1. The Commission shall be given all authority under Tennessee law to create rules to implement this section. Any rule promulgated by the Commission shall be in accordance with T.C.A. § 4-5-201 *et. seq.*

X. Savings Clause

1. If any provision of this act or its application to any person or circumstance is held invalid, then the invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to that end, the provisions of this act are severable.

IV. Annotations to the Recommended Text

In the following pages, the Commission provides commentary about matters that generated significant discussion. As it appears below each heading, the words in italics are lifted directly from the recommended text and provided as context for the discussion.

a) Definition for "acceptable form of medical cannabis"

"Acceptable form of medical cannabis" means oils, tinctures, patches, edibles, vapors, waxes and other portions of the cannabis plant and any mixture or preparation thereof that is concealed in its manufacturer's original packaging and labeling from an approved state and which meets any and all labeling and other specifications as determined by the Commission in rule, excluding, but not limited to, dried leaves, flowers, seeds, roots, stems, stalks and fan leaves.

The Commission submits this initial recommendation with nearly every form of medical cannabis available for purchase except for dried flower. The recommended language includes a catch-all provision for other forms which may be considered but are not listed. To be considered an acceptable form, the medical cannabis (product) shall be contained in its manufacturer's original packaging and labeling. This packaging and labeling shall meet or exceed the packaging and labeling requirements of the state where the medical cannabis was packaged and labeled (i.e. the approved state). Furthermore, the Commission shall articulate in rule form other specifications germane to packaging and labeling.

When looking across other jurisdictions while considering the established public policy of this State, the Commission recommends language that excludes dried flower from the acceptable form of medical cannabis.[21] The Commission understands both arguments for the allowance of flower and arguments prohibiting dried flower. While dried flower is an accessible, cost-conducive form of cannabis, flower creates difficult challenges in enforceability. Laboratory-based testing concepts for dried flower lag behind societal activities. For instance, it is impossible to tell, today, in a roadside encounter, whether dried flower inside a manufacturer's container is the dried flower *produced by* the manufacturer. As noted, significant educational measures must be taken to ensure proper awareness and training regardless of the form recommended.

As part of its role in making relevant recommendations, the Commission considered a definition for "medical cannabis" and where to place this definition. One suggestion is to place the definition in Title 39, section 17, part 4 as another exception to the current list of exceptions for "marijuana." A definition for "medical cannabis" may serve to clarify the difference between "medical cannabis" and marijuana by distinguishing what is acceptable in both form and amount. The opportunity exists to define "medical cannabis" within Title 39 to add clarity while not creating unforeseen consequences.

The Commission wished to apply the term "medical cannabis" consistently throughout its recommended text. References to "marijuana" are intended to apply to the State's definition under Title 39 (i.e. the criminal code) while references to "approved form medical cannabis" would mean an approved form in a proper amount under the recommended text. The Commission also wished for the opportunity to further explore this topic through continued research.

b) Definition for "[m]anufacturer's original packaging and labeling"

"Manufacturer's original packaging and labeling" means packaging and labeling which is compliant with the laws of the approved state, which includes seed-to-sale tracking, and the manufacturer, cultivator, processor, or distributor who packaged and/or labeled the acceptable form of medical cannabis is licensed by the appropriate oversight body in the approved state where the product is purchased.

The recommended text includes a definition to explain the concept of "manufacturer's original packaging and labeling." This term is provided for two reasons: (1) to be extremely clear what vessel must accompany any medical cannabis product and (2) to provide law enforcement with precise language about the container. The packaging and labeling shall comply with the laws of the approved state. This compliance includes seed-to-sale tracking with proper labeling. The last element of the definition is a proper license with the oversight body of the approved state.

c) Definition for "qualified medical condition"

"Qualified medical condition" means any of the following:

a) Alzheimer's disease;

b) Amyotrophic lateral sclerosis (ALS);

c) Cancer, when such disease is diagnosed as end stage or the treatment produces related wasting illness, recalcitrant nausea and vomiting, or pain;

d) Inflammatory bowel disease, including Crohn's disease and ulcerative colitis;

e) Epilepsy or seizures;

f) Multiple sclerosis;

g) Parkinson's disease;

h) Human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS);

j) Sickle cell disease; or

i) Any other disease or condition recommended by the Medical Cannabis Commission pursuant to rules promulgated by the Commission.

The General Assembly asked the Commission to "prioritize the recommendations for the creation of a patient registration process or program that includes patients with a qualifying medical disease or condition recommended by the commission."[22] Within the chapter definitions of the statutory provisions which create the Commission, the General Assembly enumerated several disease states as "[q]ualifying medical disease or condition."[23] The Commission listed the medical conditions as defined by the General

Assembly and included a provision which allows the Commission to add conditions. The Commission is respectful of its role and does not wish to overstep its bounds. The General Assembly may wish to retain authority to modify the list of enumerated medical conditions. The Commission thought it may be onerous to routinely hear requests from interested stakeholders who wish to see expansion of the list of qualifying conditions. Lastly, the Commission notes the need for requests in this arena to be standardized and uniform to allow the decisionmaker to evaluate relevant principles of medicine and pharmacology.

It should be noted, in reports already cited within this document, the Commission viewed participation metrics which increase significantly across other jurisdictions when pain and / or Post Traumatic Stress Disorder, specifically, are added to the list of qualifying medical conditions. The Commission hopes to consider patient data in the coming months to assist in determining a patient-centered approach to qualifying medical conditions.

d) Definition of reciprocity

"Approved state" means the states of Arkansas, Delaware, Missouri, Ohio, Rhode Island, and Utah. The Commission may approve other states as determined by the Commission. In adopting other states for approval, the Commission shall consider whether other states allow participation in a medical cannabis program by citizens of this state. Other considerations include provisions for seed-to-sale tracking, packaging, labeling, and a licensing structure.

The Commission adopted the phrase "approved state" to refer to states which have a reciprocity element to their medical cannabis programs but states which do not currently contain an adult-use cannabis program. The Commission will continually explore expansion of this list for the benefit of patients. This list of states are the places which a patient may obtain an acceptable form and amount of medical cannabis then return to Tennessee (with the medical cannabis) under the protection of the recommended text.[24] Furthermore, an enumerated list provides bright lines in the enforcement of criminal acts. For instance, only an acceptable form and amount of medical cannabis from an approved state would receive statutory protection under the proposed text.

The first issue considered by the Commission pertaining to reciprocity was a definition – what does reciprocity mean. The second issue, and part and parcel, is to whom reciprocity is given. Black's Law Dictionary defines reciprocity as the "mutual concession of advantages or privileges for purposes of commercial or diplomatic relations."[25] In the traditional sense as applicable to medical cannabis, a patient with a registry identification card issued in State A, the patient's home state where citizenship is obtained, may utilize the supply chain (up to and including dispensaries) in State B. By virtue of status as a cardholder (of a patient registry identification card), the patient is bestowed benefits from the visiting state. Counsel for the Commission initially indicated reciprocity could apply to both a Tennessee citizen in possession of a proper form and amount and a visitor to Tennessee who brings medical cannabis into this State. The Commission considered this approach.

Ultimately, in the scenario before the Commission, the Commission is not able to propose the conferring of rights or benefits upon the citizens of another state because the priority is placed on a patient-based system which does not contain an active supply chain model. For this reason, the Commission cannot provide a recommendation to the General Assembly for true reciprocity. The establishment of the

definition of reciprocity enabled the Commission to focus solely on Tennessee citizens as part of its recommended statutory text. There is not a final recommendation in the recommended text for visitors to Tennessee.

It should be noted there are significant law enforcement issues related to the "visitors" scenario referenced above. If the law were to allow patients of specific states to have a safe harbor in Tennessee, the enforcement of such activities becomes extremely difficult. First, there is not a broad, universal (i.e. national) database for patients. Each state with a patient registry protects its own information. Said differently, out-of-state access to a patient registry becomes possible only through judicial orders – there is not a traditional right of access. Next, the burden becomes heavy on this State if Tennessee were to create a system of registration for visitors. Beyond costs to create a database purely for visitors to this State, the time and resources necessary to train and educate all interested stakeholders becomes weighty and significant. Lastly, there would be a time lag between the initial upload to a registry, a period of time for confirmation, and a ratification of the visitor's application. Said differently, a weekend visitor to Tennessee could enter and leave Tennessee before the Commission is able to process the visitor's registry information.

While being respectful of its role and purpose, the Commission did not wish to burden the General Assembly with the need to continually add states to the list of approved states. The Commission proposed allowing the Commission to expand the list of approved states through statutorily defined criteria. These criteria, as indicated, include a determination of whether other states allow participation in a medical cannabis program by citizens of this state, provisions for seed-to-sale tracking, packaging, labeling, and an enforceable licensing structure.

e) Possession limits

A qualified patient or designated caregiver in actual possession of a qualified patient or designated caregiver identification card shall not be subject to arrest, prosecution, or penalty in any manner or denied any right or privilege, including without limitation a civil penalty or disciplinary action by a business, occupational, or professional licensing board or bureau, for the medical use of cannabis in accordance with this Chapter if the qualified patient or designated caregiver possesses an amount less than or equal to:

a) ____ grams of concentrated product; or

b) ____ milligrams of infused products

The Commission engaged in robust discussion regarding the amounts of product a qualified patient may possess. The Commission respectfully requests more opportunity to explore this key provision by virtue of expert and patient advocacy testimony coupled with relevant research. The Commission aspires to provide the General Assembly with fact-based, scientifically grounded numbers for possession limits.

A balancing must occur between the burden on the patient to obtain medical cannabis and the desire not to create significant opportunity for illicit activity. Possession limits fluctuate across the jurisdictions with two ounces (2 oz.) of dried flower appearing as a common occurrence. The state of Colorado, Department of Revenue produced a Marijuana Equivalency in Portion and Dosage white paper in August of 2015.[26]

This white paper outlines one approach in converting dosages from dried flower (which is not allowed under the recommended text) into other forms of usable medical cannabis (i.e. oils, tinctures, patches, edibles, vapors, and waxes). On page six (6) of the white paper, as a baseline approach, "347 and 413 edibles of 10mg strength can be produced from an ounce of marijuana, depending on the solvent type and production method. For concentrates, between 3.10 and 5.50 grams of concentrate are equivalent to an ounce of flower marijuana."

Using this conversion, the Commission considered three (3) milligrams of concentrated product and 300 milligrams of infused products which may be interpreted as a very low amount. The Commission also considered allowing a six-month possession limit. Higher quantities may not create unforeseen consequences given layers of protection embedded within the framework – from a qualifying medical condition to ultimate ratification by the Commission to issue a qualified patient identification card. The Commission ultimately voted to withhold a recommendation until a future time while the Commission explores this topic with deliberate intensity.

A few relevant points addressed by the Commission include possession limits versus a purchase limit and the potential for certain medial conditions or hardships to allow for a patient to possess more than the stated limit. Said differently, the Commission considered an inner cap and outer cap for possession limits. While the Commission did not vote to recommend either concept in the preceding text, the Commission hopes to evaluate this topic in the coming months. There are equal parts of concern in recommending amounts that are too low and too high. As stated, the Commission is very cognizant of the burden on the patient to travel to and from another state versus the desire to not create unintended results.

f) Protected status as a qualified patient

An employer shall not discriminate against an applicant or employee in hiring, termination, or any term or condition of employment, or otherwise penalize an applicant or employee, based upon the applicant's or employee's past or present status as a qualified patient or designated caregiver.

The recommended text begins with the concept that status as qualified patient – a person with a diagnosed medical condition – is not a basis, by itself, for adverse or discriminatory outcomes in the employment setting. An employer cannot use qualified patient status as the basis for termination. However, there is not a protected status as a *user* of medical cannabis while on site and / or on duty. A person may be a qualified patient, but the qualified patient is not protected to use medical cannabis on the employer's premises or during business hours. Furthermore, an employer may establish a Drug Free Workplace program and may act based upon a good faith belief of possession or consumption while on duty.

g) The Written Certification

The qualified physician shall register within the Patient Registry as the issuer of the written certification[.]

The Written Certification is the process whereby a qualified patient is diagnosed with a qualifying medical condition and (the patient receives) a confirmation of the diagnosis through a Commission-sanctioned portal (i.e. Patient Registry) available to a medical doctor or doctor of osteopathic medicine ("physician").

The physician enters routine licensure information in addition to the patient's name, address and date of birth in the Patient Registry. The physician then provides the medical condition. Once this entry is created, the patient has 30 days to complete the application process. Said differently, a Written Certification is valid for 30 days. The Commission accesses the Patient Registry when processing applications for a qualifying patient or designated caregiver identification card.

There is a split amongst the states regarding initiation of the patient registry process. The choices are binary: either the physician begins the process, or the patient begins the process. The Commission opined a physician's initiation would reduce opportunities for fraudulent behavior. Moreover, inefficiencies are exposed when reproduction of documentation is required. Such is the case when a patient misplaces his/her Written Certification. Under the proposed text, a physician may complete the Patient Registry process while in the examination room with linked computer systems. The cost and time allocation for the conversion to a patient portal (for the patient registry) is noted by the Commission. The burden on qualified physicians to implement the necessary software platforms for a Patient Registry is acknowledged by the Commission.

The Commission considered the possibility of allowing renewals of the Written Certification to occur through telehealth.

h) Informed Consent

A qualifying physician shall obtain the voluntary and informed written consent of the patient each time the qualified physician issues a written certification for the patient, which shall be maintained in the patient's medical record. The patient, or the patient's parent or legal guardian if the patient is a minor, must sign the informed consent acknowledging that the qualified physician has sufficiently explained its content. The qualified physician must use a standardized informed consent form adopted by the Commission, which must include, at a minimum, information related to:

a) The Federal Government's classification of medical cannabis in the federal Controlled Substance Act of 1970;

b) The approval and oversight status of medical cannabis by the Food and Drug Administration;

c) The current state of research on the efficacy of medical cannabis to treat the qualifying conditions set forth in this section;

d) The potential for addiction and resources available for addiction;

e) The potential effect that medical 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 a person to be alert or respond quickly;

f) The potential side effects of medical cannabis use, including the negative health risks associated with smoking medical cannabis; and

g) Possible limitations placed on Tennessee citizens who seek to obtain medical cannabis in another state

Depending upon the jurisdiction utilized by the patient to obtain medical cannabis, it may be that the patient does not have the opportunity to speak with a health care provider about medical cannabis as a medication. The informed consent provision within the recommended text allows for an exchange between the physician and the patient about matters relevant to cannabis as a medication. The state of Florida produced an informed consent which is attached hereto. This document is illustrative of an informed consent conversation.

The Commission expressed concerns in creating a standard which is difficult, if not impossible, to meet for purposes of compliance while also providing a level of education to patients.

i) Patient Registry

The Commission shall create and maintain a secure, electronic, and online Patient Registry for qualified physicians, qualified patients, and designated caregivers as provided under this section. The Patient Registry shall be accessible to law enforcement agencies and qualified physicians to verify the authorization of a qualified patient or a designated caregiver to possess medical cannabis. The Patient Registry must also be accessible to practitioners licensed to prescribe prescription drugs to ensure proper care for patients before medications that may interact with the medical use of cannabis are prescribed. The Patient Registry must prevent an active registration of a qualified patient by multiple physicians.

The Patient Registry is an electronic database accessible to authorized stakeholders. As noted, the Patient Registry is the first point of contact within the proposed text regarding a qualified patient or designated caregiver identification card. The Patient Registry shall operate in real time with the highest levels of security due to the storage of Protected Health Information. The proposed text authorizes access to the Patient Registry for the qualified physician, and any other person with authority to prescribe medications and law enforcement agencies.

Access for law enforcement agencies is limited to information solely necessary for ascertaining validity of the qualified patient or designated caregiver identification card. This excludes the patient's qualifying medical condition. For the protection of medical cannabis to apply to a given patient, the patient shall present a qualified patient or designated caregiver identification card to law enforcement when requested, in addition to other requirements. Should law enforcement personnel wish to verify the contents of the qualified patient or designated caregiver identification card, law enforcement personnel shall have the opportunity, in real time, to query the Patient Registry to make the confirmation.

The Commission confirms patients within the Patient Registry. One piece of this confirmation is determining citizenship status. The Commission recommends allowing a government-issued identification card to serve as one layer of identification in addition to other designated proofs.

The Commission recommends authority to suspend or revoke a qualified patient or designated caregiver identification card.

The purpose and concepts of the Patient Registry may evolve over time if there is a rescheduling or descheduling of cannabis under federal law. For instance, if health care providers begin making recommendations to patients regarding dosages and forms of medical cannabis, the Patient Registry would store this relevant information and provide law enforcement agencies access to relevant information. The Commission seeks to provide necessary access to the Patient Registry to ensure all interested stakeholders have proper, instant information. The Commission also strives to produce recommendations for bedrock concepts such as the Patient Registry.

j) Qualified patient and caregiver identification card

The Commission shall issue qualified patient or designated caregiver identification cards for qualified patients and designated caregivers who are residents of this state and who have submitted application and fee to the Commission following registration by a qualified physician.

One of the first concepts broached by the Commission involved single-source issuers of qualified patient or designated caregiver identification cards. A qualified patient or designated caregiver identification card is the end goal and result of this process through the eyes of the patient. The Commission determined very early that opportunities for nefarious activities increase significantly when multiple agencies interact in the issuance of identification cards. For this reason alone, the Commission strongly recommends a single source as the issuer of a qualified patient or designated caregiver identification card. Of the 36 states which operate a medical cannabis program considered by the Commission, only the states of California and Louisiana operate a system of card issuance which is local in nature. The remaining 34 states issue identification cards from a single source – a department of health, the cannabis oversight body, or some other governmental agency.

In an effort to propose recommendations which are self-sustaining,[27] the Commission suggests a $50 fee each time a qualified patient or designated caregiver identification card is issued either as an initial application or a renewal application. A qualified patient or designated caregiver identification card is valid for no longer than one (1) year. A replacement fee is a separate and distinct fee for the replacement of a lost qualified patient or designated caregiver identification card. The $50 fee is an attempt to offset costs of the Patient Registry and employees required to process applications. Without supply-based licensure categories, the opportunities to generate funds to support the program are extremely limited. One such occasion is a non-refundable application fee.

The length of time granted to the Commission to process an application for a qualified patient or designated caregiver is 45 days. This expressed timeline is given to facilitate the movement of applications to ward against an application becoming stale. The Commission made a number of considerations on this subject: ability to meet electronically to review and approve applications; administrative sorting of applications prior to regularly scheduled meetings; and naming a designee to sort applications. Ultimately the Commission copied language from Title 63 relevant to the processing of applications coupled with temporary authorization contingent upon a full ratification by the Commission.

k) Designated Caregivers

There are two concepts that generated discussion relative to caregivers: (1) caregiver applications and (2) caregiver compensation. Each shall be discussed individually.

(1) Caregiver applications

Caregiver applications (to the Commission) include a provision that requires the applicant caregiver to complete a caregiver course approved by the Commission. The application process also requires the applicant caregiver to submit the results of a criminal background check to the Commission. The reasoning for both notions is protection of the patient from individuals seeking to exploit vulnerable members of the population. The Commission aimed to place safeguards in the application process. Other protections include a limitation on the number of qualified patients a caregiver may serve. A caregiver may be registered for only one patient unless the patient is a child, or the caregiver and patient are both participants (as employee and patient) in a hospice program.

(2) Caregiver compensation

A designated caregiver may not receive compensation, other than actual expenses incurred, for any services provided to the qualified patient. This prohibition on compensation shall not apply to designated caregivers serving as a designated caregiver under this Chapter in conjunction with the designated caregiver's primary employment under state or federal law.

The jurisdictions split on caregiver compensation. Some states outright prohibit any compensation other than expenses while other states allow for compensation. The Commission spent significant time debating this topic. The Commission considered the burden on a patient to travel to an approved state juxtaposed with actors seeking to exploit the system for illicit gain. The Commission attempted to strike a balance and indicate a caregiver may receive compensation if administration of medical cannabis is a routine part of the caregiver's duties with the patient. The Commission did not wish to exclude those from compensation who are employed in a capacity whereby caregiving is a routine part of the job assignment. The Commission is very sensitive to the need for caregivers to potentially invest significant resources of time and money to obtain medical cannabis for the qualified patient. Simultaneously, the Commission is concerned with persons who may wish to take advantage of a qualified patient. The prohibition on compensation applies to those individuals who simply wish to accumulate a list of qualified patients for purposes of financial gain. Said differently, if a person is acting outside of his/her employment to serve as a caregiver, there is a prohibition on compensation. One reason in making mention of this topic is a deterrent for those who only seek financial gain. As referenced, the restriction on the number of caregivers is another attempt to thwart those with less than good intentions.

The Commission noted if the law allows caregivers to serve a large volume of patients, the scenario arises where the caregiver would be in lawful possession of possession limits for each patient as a designated caregiver.

l) Limitations

(1) Places of possession and consumption

The initial drafts of the recommended text included language that prohibited the possession of, or otherwise engaging in the use of, medical cannabis in certain places. These places included on a school bus; on the grounds of a daycare center, preschool, primary or secondary school, college, or university; at a drug or alcohol treatment facility; at a community or recreation center; in a correctional facility; on any form of public transportation; in a public place; or on any property that is under control of the Tennessee National Guard or the United States military. The Commission considered other controlled substances are, presumably, allowed in most of the listed places. For the most part, the law does not forbid possession of controlled substance "in a public place," for example. The Commission voted to strike the provision of its previous version which prohibited possession in specified places. The Commission determined policies of the listed places are in a better position to facilitate oversight of the possession and use of a medication.

(2) Driving under the influence of medical cannabis

The Commission reviewed a limited number of laws from jurisdictions which place a per se limit on the amount of nanograms per milliliter in the blood of a person who is operating a motor vehicle. The Commission clearly expressed a desire to include language regarding "the totality of circumstances" when evaluating impairment. This clause allows law enforcement personnel to evaluate all elements of an encounter to determine whether a person is driving under the influence.

The Commission ultimately voted to strike the per se limit. First, the science of determining impairment from biological samples of a daily user of medical cannabis is lacking. The metabolism of cannabinoids, namely THC, is not consistent and predictable from person to person, in sharp contrast to alcohol. The Commission requests more time to study per se limits. There are very few jurisdictions, nationally, that utilize per se limits. Other states use a zero-tolerance policy – any amount of THC is grounds for impaired driving. The most common approach is that which requires the driver to be under the influence or affected by THC to be considered a criminal violation.[28] Better, more precise data is needed to fully comprehend this topic and the Commission aims to address this issue over time.

m) Physician conflicts – written certification

A physician who issues a written certification shall not have an employment or direct or indirect ownership of an equity interest, including direct ownership of stock or shares form a business engaged in in cultivation, processing, shipping, or distribution of cannabis for medical use and shall be referred to the proper license board for disciplinary action under the applicable practice act for issuing such written certification while in possession of employment or direct or indirect ownership of an equity interest[.]

The Commission considered the issue of physician conflicts on several occasions. Counsel for the Commission suggested a bright-line approach to identifying the boundaries. In this circumstance, as the law evolves in this area, the Commission wished to begin a process where those who make certifications cannot also hold a financial interest in the issuance of written certifications. The Commission is aware of

the nature of financial investments coupled with the depth and breadth of opportunities to invest. In the event federal law changes, this provision shall serve as the basis for an anti-kick back approach.

n) Final notes

The Commission wishes to express to the General Assembly final notes it has learned about the need for education and the increased need for Law enforcement personnel.

Should the General Assembly pass (and the governor sign) legislation based upon the Commission's recommendations, the Commission notes the need to educate patients, health care providers, and law enforcement personnel. It is clear to the Commission that patient education is needed to explain the concepts of impaired driving, the lasting impacts of THC within the human body (as it relates to impairment), and the consequences of driving under the influence of THC. The public at large shall benefit from educational promotions aimed to increase awareness for patients.

Education is also needed for health care professionals. The addition of medical cannabis as a medication presents potential contraindications and potentiators. While the role of a health care provider is limited in this initial recommendation, the Commission notes ground-level education to health care providers may pay dividends with the evolution of medical cannabis.

The most significant level of education occurs with law enforcement personnel. Law enforcement personnel must understand the concepts of approved states, acceptable form of medical cannabis, allowable amounts, the patient registry system, and the signs of impairment. Some of these concepts are crossovers from duties currently assigned. Some of these concepts are new. Regardless of status, law enforcement personnel must learn and apply an entirely new set of laws. Part and parcel to education is an increase in need for specialized law enforcement personnel. Trainings shall be necessary for education and specializations. Lt. Standford highlighted the value of a drug recognition expert. Director Lyttle demonstrated the value in exceptional employees who work in technical matters of criminal law. These changes carry a substantial fiscal impact. The Commission brings these matters to the attention of the General Assembly.

The Commission respectfully reports to the Tennessee General Assembly, the chief clerks of the Senate and the House of Representatives and the legislative librarian, as stated herein, this the 4th day of January, 2022, by and through its elected chairperson – Dr. Steve Dickerson.

/s/ Steve Dickerson, M.D.
Steve Dickerson, M.D.
Chairperson – Tennessee Medical Cannabis Commission

End Notes

[1] T.C.A. § 68-7-109(b)

[2] T.C.A. § 68-7-109(c)

[3] T.C.A. § 68-7-102(a).

[4] T.C.A. § 68-7-109(c)

[5] States use the term "medical cannabis" and "medical marijuana" to refer to the same plant and corresponding regulatory scheme. To the extent the terms appear in this report, the terms may be used interchangeably.

[6] This list is not all inclusive. Several states offer different variations of a medical program without an adult-use program.

[7] AR Const. amend. 98, § 2(13) and (17)(A)

[8] AR Const. amend. 98, § 3(a)

[9] Arkansas Department of Health 2020 Medical Marijuana Fiscal Year Report https*://www.healthy.arkansas.gov/images/uploads/publications/FY_2020_MMJ_Report_V.11.25.2020.pdf*

[10] Office of Medical Marijuana Use Weekly Update October 29, 2021 *https://knowthefactsmmj.com/wp-content/uploads/ommu_updates/2021/102921-OMMU-Update.pdf*

[11] Section 381.986(14)(a), Florida Statutes (2021)

[12] Section 381.986(8)(e)(7), Florida Statutes (2021)

[13] Section 381.986(5)(b)(2), Florida Statutes (2021)

[14] Article XIV, section 1, of the Missouri Constitution

[15] Missouri Department of Health and Senior Services Medical Marijuana Regulatory Program 2020 Annual Report *https://health.mo.gov/safety/medical-marijuana/pdf/annual-mmrp-report-governor-py20.pdf*

[16] Ohio Rev. Code Ann. § 3796.06(B)(1) and (2)

[17] Ohio Rev. Code Ann. § 3796.16(A)(1)

[18] Ohio Board of Pharmacy Medical Marijuana Plant Material Days-Supply Dispensation Reference Standard and Terminal Reference *https://medicalmarijuana.ohio.gov/Documents/LicenseeResources/Dispensary%20Licensee%20Resources/DISPENSARY%20TECHNOLOGY%20&%20SYSTEMS/Plant%20Material%20Days%20Supply%20Reference.pdf*

[19] Okla. Stat. tit. 63, § 420(m)

[20] Oklahoma Medical Marijuana Authority Medical Marijuana Revenue (December 2021) *https://stories.opengov.com/oklahomastate/published/XKuMf5_Q1*

[21] T.C.A. § 39-17-402(16)

[22] T.C.A. § 68-7-109(b)

[23] T.C.A. § 68-7-101(5)

[24] Marihuana (SIC) is a Schedule I substance under the federal Controlled Substances Act. Possession and interstate transportation of a Schedule I substance are illegal under federal law. 18 U.S.C. § 1952; 21 U.S.C. § 812(c); 21 U.S.C. §841 and 21 U.S.C. §844.

[25] *Reciprocity* Black's Law Dictionary (11th ed. 2019)

[26] State of Colorado, Department of Revenue Marijuana Equivalency in Portion and Dosage (August 10, 2015) *https://www.colorado.gov/pacific/sites/default/files/MED%20Equivalency_Final%2008102015_1.pdf*

[27] T.C.A. § 68-7-109(c)

[28] National Conference of State Legislatures Drugged Driving / Marijuana-Impaired Driving (September 23, 2021) *https://www.ncsl.org/research/transportation/drugged-driving-overview.aspx*

Informed Consent

State of Florida

January 4, 2022

Medical Marijuana Consent Form

A qualified physician may not delegate the responsibility of obtaining written informed consent to another person. The qualified patient, or the patient's parent or legal guardian if the patient is a minor, must initial each section of this consent form to indicate that the physician explained the information and, along with the qualified physician, must sign and date the informed consent form.

This consent form contains three parts. Part A must be completed by all patients. Part B is only required for patients under the age of 18 with a diagnosed terminal condition who receive a certification for medical marijuana in a smokable form. Part C is the signature block and must be completed by all patients.

Part A: Must be completed for all medical marijuana patients

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

_____ The federal government has classified marijuana as a Schedule I controlled substance. Schedule I substances are defined, in part, as having (I) a high potential for abuse; (2) no currently accepted medical use in treatment in the United States; and (3) a lack of accepted safety for use under medical supervision. Federal law prohibits the manufacture, distribution and possession of marijuana even in states, such as Florida, which have modified their state laws to treat marijuana as a medicine.

_____ When in the possession of medical marijuana, the patient or the patient's caregiver must have his or her medical marijuana use registry identification card in his or her possession at all times.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

_____ Marijuana has not been approved by the Food and Drug Administration for marketing as a drug. Therefore, the "manufacture" of marijuana for medical use is not subject to any federal standards, quality control, or other federal oversight. Marijuana may contain unknown quantities of active ingredients, which may vary in potency, impurities, contaminants, and substances in addition to THC, which is the primary psychoactive chemical component of marijuana.

c. The potential for addiction.

_____ Some studies suggest that the use of marijuana by individuals may lead to a tolerance to, dependence on, or addiction to marijuana. I understand that if I require increasingly higher doses to achieve the same benefit or if I think that I may be developing a dependency on marijuana, I should contact Dr._____(name of qualified physician).

d. The potential effect that marijuana 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 a person to be alert or respond quickly.

_____ The use of marijuana can affect coordination, motor skills and cognition, i.e., the ability to think, judge and reason. Driving under the influence of cannabis can double the risk of vehicular accident, which escalates if alcohol is also influencing the driver. While using medical marijuana, I should not drive, operate heavy machinery or engage in any activities that require me to be alert and/or respond quickly and I should not participate in activities that may be dangerous to myself or others. I

understand that if I drive while under the influence of marijuana, I can be arrested for "driving under the influence."

e. The potential side effects of medical marijuana use.

_____ Potential side effects from the use of marijuana include, but are not limited to, the following: dizziness, anxiety, confusion, sedation, low blood pressure, impairment of short term memory, euphoria, difficulty in completing complex tasks, suppression of the body's immune system, may affect the production of sex hormones that lead to adverse effects, inability to concentrate, impaired motor skills, paranoia, psychotic symptoms, general apathy, depression and/or restlessness. Marijuana may exacerbate schizophrenia in persons predisposed to that disorder. In addition, the use of medical marijuana may cause me to talk or eat in excess, alter my perception of time and space and impair my judgment. Many medical authorities claim that use of medical marijuana, especially by persons younger than 25, can result in long-term problems with attention, memory, learning, drug abuse, and schizophrenia.

There is substantial evidence of a statistical association between long-term cannabis smoking and worsening respiratory symptoms and more frequent chronic bronchitis episodes. Smoking marijuana is associated with large airway inflammation, increased airway resistance, and lung hyperinflation. Smoking cannabis, much like smoking tobacco, can introduce levels of volatile chemicals and tar in the lungs that may raise concerns about the risk of cancer and lung disease.

_____ I understand that using marijuana while consuming alcohol is not recommended. Additional side effects may become present when using both alcohol and marijuana.

_____ I agree to contact Dr. _____ if I experience any of the side effects listed above, or if I become depressed or psychotic, have suicidal thoughts, or experience crying spells. I will also contact Dr._____if I experience respiratory problems, changes in my normal sleeping patterns, extreme fatigue, increased irritability, or begin to withdraw from my family and/or friends.

f. **The risks, benefits, and drug interactions of marijuana**.

_____ Signs of withdrawal can include: feelings of depression, sadness, irritability, insomnia, restlessness, agitation, loss of appetite, trouble concentrating, sleep disturbances and unusual tiredness.

_____ Symptoms of marijuana overdose include, but are not limited to, nausea, vomiting, hacking cough, disturbances in heart rhythms, numbness in the hands, feet, arms or legs, anxiety attacks and incapacitation. If I experience these symptoms, I agree to contact Dr. _____ immediately or go to the nearest emergency room.

_____ Numerous drugs are known to interact with marijuana and not all drug interactions are known. Some mixtures of medications can lead to serious and even fatal consequences.

I agree to follow the directions of Dr._____regarding the use of prescription and non-prescription medication. I will advise any other of my treating physician(s) of my use of medical marijuana.

_____ Marijuana may increase the risk of bleeding, low blood pressure, elevated blood sugar, liver enzymes, and other bodily systems when taken with herbs and supplements. I agree to contact Dr. _____ immediately or go to the nearest emergency room if these symptoms occur.

_____ I understand that medical marijuana may have serious risks and may cause low birthweight or other abnormalities in babies. I will advise Dr._____if I become pregnant, try to get pregnant, or will be breastfeeding.

g. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

___ Cancer

- There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancers, including glioma.

  There is evidence to suggest that cannabinoids (and the endocannabinoid system more generally) may play a role in the cancer regulation processes. Due to a lack of recent, high quality reviews, a research gap exists concerning the effectiveness of cannabis or cannabinoids in treating cancer in general.

- There is conclusive evidence that oral cannabinoids are effective antiemetics in the treatment of chemotherapy-induced nausea and vomiting.

  There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancer-associated anorexia-cachexia syndrome and anorexia nervosa.

___ Epilepsy

- There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for epilepsy.

  Recent systematic reviews were unable to identify any randomized controlled trials evaluating the efficacy of cannabinoids for the treatment of epilepsy. Currently available clinical data therefore consist solely of uncontrolled case series, which do not provide high-quality evidence of efficacy. Randomized trials of the efficacy of cannabidiol for different forms of epilepsy have been completed and await publication.

___ Glaucoma

- There is limited evidence that cannabinoids are an ineffective treatment for improving intraocular pressure associated with glaucoma.

  Lower intraocular pressure is a key target for glaucoma treatments. Nonrandomized studies in healthy volunteers and glaucoma patients have shown short-term reductions in intraocular pressure with oral, topical eye drops, and intravenous cannabinoids, suggesting the potential for therapeutic benefit. A good-quality systemic review identified a single small trial that found no effect of two cannabinoids, given as an oromucosal spray, on intraocular pressure. The quality of evidence for the finding of no effect is limited. However, to be effective, treatments targeting lower intraocular pressure must provide continual rather than transient reductions in intraocular

pressure. To date, those studies showing positive effects have shown only short-term benefit on intraocular pressure (hours), suggesting a limited potential for cannabinoids in the treatment of glaucoma.

___ Positive status for human immunodeficiency virus

- There is limited evidence that cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS.

  There does not appear to be good-quality primary literature that reported on cannabis or cannabinoids as effective treatments for AIDS wasting syndrome.

___ Acquired immune deficiency syndrome

- There is limited evidence that cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS.

  There does not appear to be good-quality primary literature that reported on cannabis or cannabinoids as effective treatments for AIDS wasting syndrome.

___ Post-traumatic stress disorder

- There is limited evidence (a single, small fair-quality trial) that nabilone is effective for improving symptoms of posttraumatic stress disorder

  A single, small crossover trial suggests potential benefit from the pharmaceutical cannabinoid nabilone. This limited evidence is most applicable to male veterans and contrasts with non-randomized studies showing limited evidence of a statistical association between cannabis use (plant derived forms) and increased severity of posttraumatic stress disorder symptoms among individuals with posttraumatic stress disorder. There are other trials that are in the process of being conducted and if successfully completed, they will add substantially to the knowledge base.

___ Amyotrophic lateral sclerosis

- There is insufficient evidence that cannabinoids are an effective treatment for symptoms associated with amyotrophic lateral sclerosis.

  Two small studies investigated the effect of dronabinol on symptoms associated with ALS. Although there were no differences from placebo in either trial, the sample sizes were small, the duration of the studies was short, and the dose of dronabinol may have been too small to ascertain any activity. The effect of cannabis was not investigated.

___ Crohn's disease

- There is insufficient evidence to support or refute the conclusion that dronabinol is an effective treatment for the symptoms of irritable bowel syndrome.

  Some studies suggest that marijuana in the form of cannabidiol may be beneficial in the treatment of inflammatory bowel diseases, including Crohn's disease.

____ Parkinson's disease

- There is insufficient evidence that cannabinoids are an effective treatment for the motor system symptoms associated with Parkinson's disease or the levodopainduced dyskinesia.

Evidence suggests that the endocannabinoid system plays a meaningful role in certain neurodegenerative processes; thus, it may be useful to determine the efficacy of cannabinoids in treating the symptoms of neurodegenerative diseases. Small trials of oral cannabinoid preparations have demonstrated no benefit compared to a placebo in ameliorating the side effects of Parkinson's disease. A seven-patient trial of nabilone suggested that it improved the dyskinesia associated with levodopa therapy, but the sample size limits the interpretation of the data. An observational study demonstrated improved outcomes, but the lack of a control group and the small sample size are limitations.

____ Multiple sclerosis

- There is substantial evidence that oral cannabinoids are an effective treatment for improving patient-reported multiple sclerosis spasticity symptoms, but limited evidence for an effect on clinician-measured spasticity.

Based on evidence from randomized controlled trials included in systematic reviews, an oral cannabis extract, nabiximols, and orally administered THC are probably effective for reducing patient-reported spasticity scores in patients with MS. The effect appears to be modest. These agents have not consistently demonstrated a benefit on clinician-measured spasticity indices.

____ Medical conditions of same kind or class as or comparable to the above qualifying medical conditions

- The qualifying physician has provided the patient or the patient's parent or legal guardian a summary of the current research on the efficacy of marijuana to treat the patient's medical condition.
- The summary is attached to this informed consent as Addendum_____.

____ Terminal conditions diagnosed by a physician other than the qualified physician issuing the physician certification

- The qualifying physician has provided the patient or the patient's caregiver a summary of the current research on the efficacy of marijuana to treat the patient's terminal condition.
- The summary is attached to this informed consent as Addendum_____.

____ Chronic nonmalignant pain

- There is substantial evidence that cannabis is an effective treatment for chronic pain in adults.

The majority of studies on pain evaluated nabiximols outside the United States. Only a handful of studies have evaluated the use of cannabis in the United
States. and all of them evaluated cannabis in flower form provided by the National Institute on Drug Abuse. In contrast, many of the cannabis products that are sold in state-regulated markets bear little resemblance to the products that are available for research at the federal level in the United States. Pain patients also use topical forms.

While the use of cannabis for the treatment of pain is supported by well controlled clinical trials, very little is known about the efficacy, dose, routes of administration, or side effects of commonly used and commercially available cannabis products in the United States.

h. That the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

_____ The Department of Health submits a data set to the Consortium for Medical Marijuana Clinical Outcomes Research for each patient registered in the medical marijuana use registry that includes the patient's qualifying medical condition and the daily dose amount and forms of marijuana certified for the patient.

PART B: Certification for medical marijuana in a smokable marijuana for a patient under 18 with a diagnosed terminal condition.

____ Initial here if you are not a patient under 18 with a diagnosed terminal condition who will be receiving medical marijuana in a smokable form. After initialing here, complete part C.

If the patient is under 18, has a diagnosed terminal condition, and will be receiving medical marijuana in a smokable form, please review and initial the remainder of Part B before completing Part C.

Respiratory Health

____ Exposures to tobacco smoke and household air pollution consistently ranks among the top risk factors not only for respiratory disease burden but also for the global burden of disease. Given the known relations ships between tobacco smoking and multiple respiratory conditions, one could hypothesize that long-term cannabis smoking leads to similar deleterious effects of respiratory health, and some investigators ague that cannabis smoking may be even more harmful that of tobacco smoking. Data collected from 15 volunteers suggest that smoking one cannabis joint can lead to four times the exposure to carbon monoxide and three to five times more tar deposition than smoking a single cigarette.

Cognitive and Psychosocial Development

____ Researchers are still studying the long-term health effects of marijuana. Most people agree that marijuana use hurts adolescents more than adults. It is during the period of adolescence and young adulthood that the neural substrates that underlie the development of cognition are most active. Adolescence marks one of the most impressive stretches of neural and behavioral change with substantial a protracted development in terms of both brain structure and function. As a result, cannabis and other substance use during this period may incur relatively greater interference in neural, social, and academic functioning compared to late developmental periods.

- There is moderate evidence of a statistical association between acute cannabis use and impairment in the cognitive domains of learning, memory, and attention.
- There is limited evidence of a statistical association between sustain abstinence form cannabis use and impairments in the cognitive domains of learning, memory, and attention.

- There is limited evidence of a statistical association between cannabis use and impaired academic achievement and education outcomes.

- There is limited evidence of a statistical association between cannabis use and increased rates of unemployment and/or low income.

- There is limited evidence of a statistical association between cannabis use and impaired social functioning or engagement in developmentally appropriate social roles.

Addiction

Marijuana, like some other brain-altering substances, can be addictive. Nearly one in 10 marijuana users will become addicted. Starting to use marijuana at a younger age can lead to a greater risk of developing a substance use disorder later in life. Adolescents who begin using marijuana before age 18 are four to seven times more likely than adults to develop a marijuana use disorder.

Part C: For certification of smoking marijuana as an appropriate route of administration for a qualified patient, other than a patient diagnosed with a terminal condition

____ **Acknowledgement of contaminant risks.**

Smokable marijuana has infectious risks that are not present in processed products. Certain molds and mildews can contaminate marijuana plants during growing, processing, storage in dispensaries and in patient homes. These contaminates can pose health risks, particularly to those who are immunosuppressed due to their disease state and treatments. While the State of Florida requires third party testing you should still inspect your product.

____ **Respiratory Health.**

Exposures to tobacco smoke and household air pollution consistently ranks among the top risk factors not only for respiratory disease burden but also for the global burden of disease. Given the known relations ships between tobacco smoking and multiple respiratory conditions, one could hypothesize that long-term marijuana smoking leads to similar deleterious effects of respiratory health, and some investigators ague that marijuana smoking may be even more harmful that of tobacco smoking.

____ **Information regarding health risks of 2nd and 3rd hand smoke to other household members.**

You should never smoke medical marijuana around other family members, especially children and any household guests. You should smoke outside to allow adequate ventilation and to mitigate the dangers of secondhand and thirdhand smoke to others. Marijuana should never be smoked inside vehicles or other small spaces that children will occupy even if the children are not present at the time the product is consumed.

____ **Dangers of smoking marijuana in households where oxygen is in use.**

If you use oxygen or have others in your household who use oxygen you should not smoke marijuana or any other combustible material in the vicinity of where the oxygen is in use due to the risk of fire and explosion.

____ **Self-dosing, if permitted.**

I have been given instructions or discussed guidance on self- dosing with my qualified physician if permitted to do so.

Part D: Must be completed for all medical marijuana patients

_____ I have had the opportunity to discuss these matters with the physician and to ask questions regarding anything I may not understand or that I believe needed to be clarified. I acknowledge that Dr._____has informed me of the nature of a recommended treatment, including but not limited to, any recommendation regarding medical marijuana.

Dr._____also informed me of the risks, complications, and expected benefits of any recommended treatment, including its likelihood of success and failure. I acknowledge that Dr. _____informed me of any alternatives to the recommended treatment, including the alternative of no treatment, and the risks and benefits. Dr. _____ has explained the information in this consent form about the medical use of marijuana.

Patient (print name) _____

Patient signature or signature of the parent or legal guardian if the patient is a minor:

_____ Date _____

I have explained the information in this consent form about the medical use of marijuana to _____ (Print patient name).

Qualified physician signature:

_____ Date _____

Witness:

_____ Date_____

64B8-9.018, F.A.C.
64815-14.013, F.A.C.
DH-MQA-5026 (Rev. 03/21)