

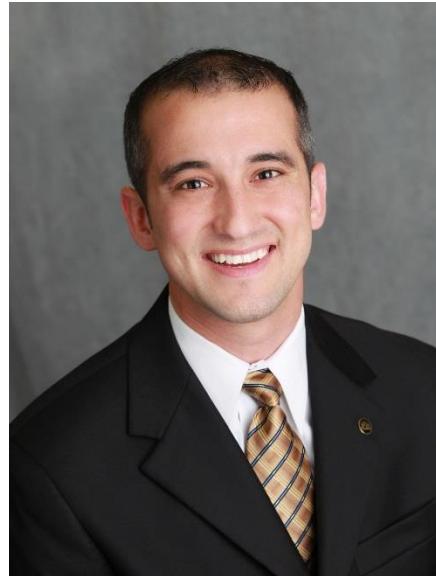


STAY ENGAGED. STAY INFORMED.

222

**TUESDAY, AUGUST 14:
STATUS OF THE NEW
CANNABIDIOL PROGRAM**

WELCOME



Anthony Pudlo, PharmD,
MBA, BCACP
Vice President of Professional Affairs
Iowa Pharmacy Association

PRESENTERS



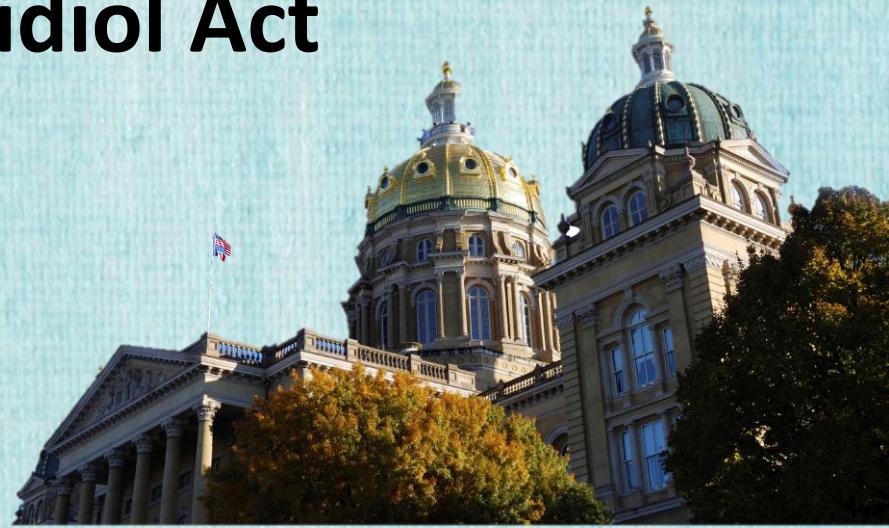
Owen Parker, MPH
Program Manager
Office of Medical Cannabidiol
Iowa Department of Public Health



Randy Mayer, MS, MPH
Director
Office of Medical Cannabidiol
Iowa Department of Public Health

House File 524 – Iowa Code 124E

Iowa Medical Cannabidiol Act



Office of Medical Cannabidiol
IOWA DEPARTMENT OF PUBLIC HEALTH
Protecting and Improving the Health of Iowans



Randy Mayer, MS, MPH

Director, Office of Medical Cannabidiol
Chief, Bureau of HIV, STD, and Hepatitis

Iowa Code 124E provides that:

A person may knowingly or intentionally:

- recommend,
- possess,
- use,
- dispense,
- deliver,
- transport, or
- administer cannabidiol.

if the recommendation, possession, use, dispensing, delivery, transporting, or administering is in accordance with the provisions of Iowa Code Chapter 124E and 641 Iowa Administrative Code 154.

Medical Cannabidiol

Medical Cannabidiol is defined as:

- any pharmaceutical-grade cannabinoid found in the plant *Cannabis sativa* L. or *Cannabis indica*; or
- any other preparation thereof that has a tetrahydrocannabinol (THC) level of no more than 3%; and
- is delivered in a form recommended by the Medical Cannabidiol Board, approved by the Board of Medicine, and put into administrative rule by the Iowa State Board of Health.

Components of the Law

- Convening of Medical Cannabidiol Board
- Issuance of patient and primary caregiver registration cards
- Licensing of two in-state manufacturers
- Licensing of up to five in-state dispensaries
- Establishment of fees for patients, caregivers, manufacturers, and dispensaries
- Monitoring of manufacturing and dispensing of CBD and other cannabinoids
- Provision of some legal protections (state) for patients, caregivers, physicians and their attorneys

Medical Cannabidiol Board

Medical Cannabidiol Board

The board comprises eight practitioners representing the fields of:

- neurology;
- pain management;
- gastroenterology;
- oncology;
- psychiatry;
- pediatrics;
- family medicine; and
- pharmacy.

Practitioners shall be licensed in Iowa, nationally board-certified in their area of specialty, and knowledgeable about the use of medical cannabidiol.

The board also has one representative from law enforcement.

Appointed Board Members

Medical Cannabidiol Board Members

Law Enforcement (chair): Mike McKelvey, Mason City

Pediatrician: Dr. Ken Cheyne, Clive

Psychiatrist: Dr. Jill Liesveld, Coralville

Family Medicine: Dr. Lonny Miller, Creston

Pharmacist: Dr. Stephen Richards, Spirit Lake

Oncologist: Dr. Robert Shreck, Des Moines

Pain Management: Dr. Jacqueline Stoken, Waukee

Neurologist: Dr. Wendy Zadeh, Ankeny

Gastroenterologist: Dr. Archana Verma, West Des Moines

Board Duties

1. **Accepting and reviewing petitions** to add medical conditions, medical treatments, or debilitating diseases for which the use of medical cannabidiol would be medically beneficial;
2. Making **recommendations to the Board of Medicine** regarding **additions to or deletions from** the list of qualifying debilitating medical conditions;
3. Working with the Department on **licensure requirements and procedures**;
4. Advising regarding the **manufacturer and dispensing locations** across the state; and

Board Duties

5. Making **recommendations** to the Board of Medicine **on the form and quantity** of allowable medical cannabidiol uses.
6. **Submitting a report** detailing the activities of the board by January 1 of each year, beginning January 1, 2018.
7. Considering whether to **recommend a statutory revision** to the definition of medical cannabidiol in Iowa Code Chapter124E that **increases the THC level to more than 3%**.

Registration Card Application Process

Card Approval and Issuance

Approval for medical cannabidiol registration cards is provided to eligible patients and their designated primary caregivers through an application process managed by the **Iowa Department of Public Health**.

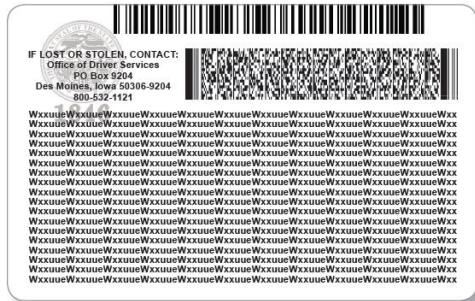
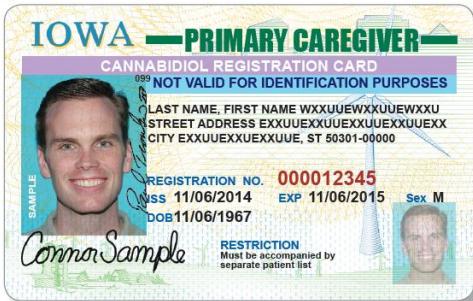
Issuance of cards to approved applicants is performed by the **Iowa Department of Transportation** at any Iowa Driver's License Issuance Station.

Once issued, cards are effective for 365 days from the date of issuance.

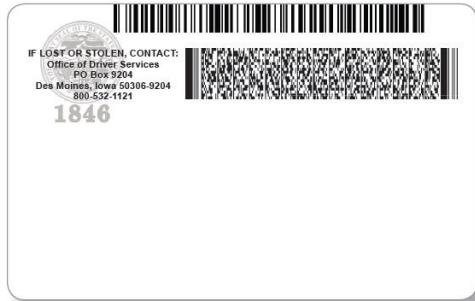
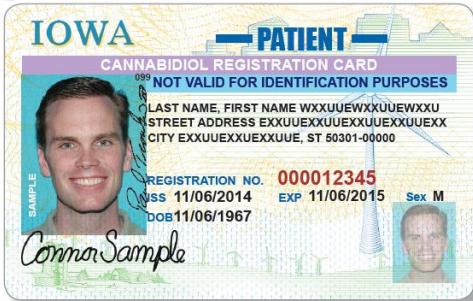
Applicants may apply for another card beginning 60 days prior to expiration of their existing card.

Registration Cards

7



8

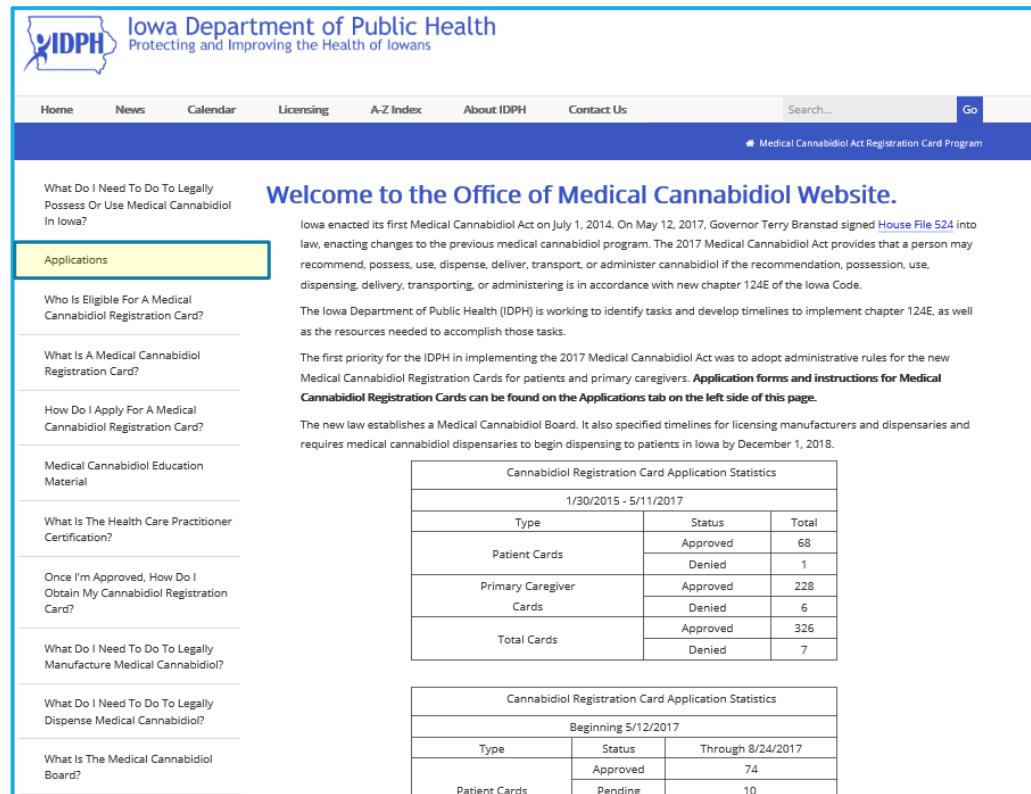


Registration Card Process

The patient and/or primary caregiver initiates the card application process.

Application forms are available on the Iowa Department of Public Health Website at:

<https://idph.iowa.gov/mcarcp>



The screenshot shows the Iowa Department of Public Health website with a blue header bar. The header includes the IDPH logo, the text "Iowa Department of Public Health Protecting and Improving the Health of Iowans", and a search bar. Below the header, a blue navigation bar has links for Home, News, Calendar, Licensing, A-Z Index, About IDPH, Contact Us, and a "Medical Cannabidiol Act Registration Card Program". The main content area has a sub-header "Welcome to the Office of Medical Cannabidiol Website." and a paragraph about the 2014 Medical Cannabidiol Act. To the left, a sidebar titled "Applications" lists various links: "What Do I Need To Do To Legally Possess Or Use Medical Cannabidiol In Iowa?", "Who Is Eligible For A Medical Cannabidiol Registration Card?", "What Is A Medical Cannabidiol Registration Card?", "How Do I Apply For A Medical Cannabidiol Registration Card?", "Medical Cannabidiol Education Material", "What Is The Health Care Practitioner Certification?", "Once I'm Approved, How Do I Obtain My Cannabidiol Registration Card?", "What Do I Need To Do To Legally Manufacture Medical Cannabidiol?", and "What Is The Medical Cannabidiol Board?". To the right, there are two tables: "Cannabidiol Registration Card Application Statistics" for the period 1/30/2015 - 5/11/2017, and "Cannabidiol Registration Card Application Statistics" for the period Beginning 5/12/2017.

Cannabidiol Registration Card Application Statistics		
1/30/2015 - 5/11/2017		
Type	Status	Total
Patient Cards	Approved	68
	Denied	1
Primary Caregiver Cards	Approved	228
	Denied	6
Total Cards	Approved	326
	Denied	7

Cannabidiol Registration Card Application Statistics		
Beginning 5/12/2017		
Type	Status	Through 8/24/2017
Patient Cards	Approved	74
	Pending	10

Patient

Means a person who has one or more of the qualifying debilitating medical conditions and:

- Is of any age;
- Is a permanent resident of Iowa;
- Has not been convicted of a disqualifying felony offense (related to possession, use, or distribution of a controlled substance).

Patient Application Process (Paper-Based)

1. Submit an application form to the Department
2. Submit a written certification to the department signed by the patient's health care practitioner that the patient is suffering from a debilitating medical condition.
3. Attest that the patient has not been convicted of a disqualifying felony offense.
4. Submit a medical cannabidiol registration fee of \$100, or a reduced fee of \$25 (recipients of social security disability benefits (SSDI), supplemental security insurance (SSI) payments, or Medicaid)

Patient Application (Paper-Based)

Sections:

- Patient Information
- Primary Care Giver Designation – Optional
- Health Care Practitioner Section
- Health Care Practitioner Certification
- Patient Application Checklist
- *We are totally changing and separating these forms

\$100/\$25 application fee



IOWA DEPARTMENT OF PUBLIC HEALTH

Office of Medical Cannabidiol

For the most current information regarding this application, medical cannabidiol laws in the state of Iowa and more, see the official website: <https://idph.iowa.gov/mcarcp>

MEDICAL CANNABIDIOL REGISTRATION CARD – PATIENT APPLICATION

Mail completed application and required materials to: Iowa Department of Public Health ATTN: OMC 321 E. 12th Street Des Moines, IA 50319-0075		<input type="checkbox"/> New Patient	<input type="checkbox"/> Renewing Patient
		Have you ever applied for a Medical Cannabidiol Registration Card in Iowa? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Print clearly. Incomplete applications may be denied. Application fees are non-returnable.			
PATIENT INFORMATION			
Name (Last, First, Middle Initial)			
Sex Designation <input type="checkbox"/> Male <input type="checkbox"/> Female		Date of Birth (Must be 18 or Older)	Age
Where You Live	Permanent Iowa Address (Street, Apt. #) Address (City, State ZIP Code)		
Where You Get Mail	Address (P.O. Box, Apt. #) Address (City, State ZIP Code)		
Primary Phone Number		<input type="checkbox"/> Check this box if a confidential message may be left at this number.	
Secondary Phone Number		<input type="checkbox"/> Check this box if a confidential message may be left at this number.	

PATIENT ATTESTATION STATEMENT

PATIENT INSTRUCTION: Complete and sign the following release statement. This statement will allow the Office of Medical Cannabidiol staff to verify information with the certifying physician(s) relating to your qualifying debilitating medical condition, and the dispensing of cannabidiol related to that condition. It will also allow the Office to complete the processing of your application and issuance of your Medical Cannabidiol Registration Card.

I, _____, (patient), hereby authorize the Iowa Department of Public Health (IDPH), Office of Medical Cannabidiol, to exchange information about my qualifying debilitating medical condition with my certifying health care practitioner, the Iowa-licensed medical cannabidiol dispensaries, and the Department of Transportation in relation to the issuance of a Medical Cannabidiol Registration Card, and the dispensing of any cannabidiol/cannabinoid product.

By signing below, I certify that the information on this application is complete, true and submitted for the purpose of obtaining a State of Iowa Medical Cannabidiol Registration Card. If approved for the Registration Card, I agree to the terms of the Iowa Medical Cannabidiol Act, Chapter 124E. A copy of the act may be found at this web address: <https://idph.iowa.gov/mcarcp>

- **To ensure confidentiality, information regarding application status will not be given over the phone.** Once applications are processed, communication will be sent to the Patient's residence with further instructions for the finalization of the Registration Card.
- You are required by law to notify the Iowa Department of Public Health Office of Medical Cannabidiol with any changes in information within 10 days of the change.
- Any Registration Card that is lost or stolen must be reported to the Office of Medical Cannabidiol immediately.
- Patient information changes that are printed on the Registration Card (such as name or address) will require a new card to be issued.

Online Patient Application (In Development, Near Completion)

- Being created by our state-system vendor, BioMauris
- Visit your doctor to get your forms filled out, go to the online form, attach the necessary documents, submit
- Greatly improve efficiency and turn-around time

1.



Iowa Department of Public Health
Protecting and Improving the Health of Iowans

IOWA PATIENT MEDICAL CANNABIS ENROLLMENT PROCESS

Thank You for your Interest [Enroll Here](#)

OMC Enrollment

Who is eligible for a Medical Cannabidiol Registration Card?

Patients who are age 18 or older, permanent residents of the state of Iowa, and have at least one of the following qualifying debilitating medical conditions:

Cancer (with severe or chronic pain, nausea or severe vomiting, cachexia or severe wasting);

Multiple sclerosis with severe and persistent muscle spasms;

Seizures;

AIDS or HIV (as defined in Iowa Code, section 141A.1);

Crohn's disease;

Amyotrophic lateral sclerosis (ALS);

Any terminal illness, with a probable life expectancy of under one year (if the illness or its treatment produces one or more of the following: severe or chronic pain, nausea or severe vomiting; cachexia or severe wasting);

Parkinson's disease;

Untreatable pain

OR

Primary Caregivers who are age 18 or older, permanent residents of the state of Iowa or a bordering state who has been designated by a patient's health care practitioner as a necessary caretaker taking responsibility for managing the well-being of the patient with res

How do I submit my application for a Medical Cannabidiol Registration Card

Submit your application by clicking on the Enrollment link above.

OR

Download the applicable application and instructions here and follow the directions for submission by mail.

Or submit your info and scanned prescription through our [online form](#). Please note: we do not accept payment online, so you will receive a phone call within 1-2 business days to complete your order.

What happens after I submit my application?

2.

Patient Application

Required Fields. Additional information may be requested in order to complete your account.

New or Renewal Application?

Patient's First Name *

Patient's Middle Name

Patient's Last Name *

Pick your gender designation

Birth Date (M/M/YY/YY) *

Primary Phone *

Secondary Phone

Enter Valid Email Address *

Check this box if a confidential message may be left at this number.

Check this box if a confidential message may be left at this number.

Select your primary contact method *

Home Address

Street Address *

City * State Zipcode *

Mailing Address: (optional)

My Home and Mailing Address are the Same.

Street Address

City State Zipcode

Street Address

City State Zipcode

Qualifying Debilitating Medical Conditions

- A. **Cancer**, if the underlying condition or treatment produces one or more of the following:
 - (1) Severe or chronic pain.
 - (2) Nausea or severe vomiting.
 - (3) Cachexia or severe wasting.
- B. **Multiple Sclerosis** with severe and persistent muscle spasms.
- C. **Seizures**, including those characteristic of epilepsy.
- D. **HIV/AIDS** as defined in Iowa Code Section 141A.1.
- E. **Crohn's Disease**.
- F. **Amyotrophic Lateral Sclerosis**.

Qualifying Debilitating Medical Conditions

- G. **Any terminal illness, with a probable life expectancy of under one year**, if the illness or its treatment produces one or more of the following:
 - (1) Severe or chronic pain.
 - (2) Nausea or severe vomiting.
 - (3) Cachexia or severe wasting.
- H. **Parkinson's Disease.**
- I. **Untreatable pain** (*any pain whose cause cannot be removed and, according to generally accepted medical practice, the full range of pain management modalities appropriate for the patient has been used without adequate result or with intolerable side effects.*)

Primary Caregiver

Means a person who:

- Is a resident of this state or a bordering state (Illinois, Minnesota, Missouri, Nebraska, South Dakota, or Wisconsin);
- Is at least 18 years of age; and
- Is a patient's parent or legal guardian, or another individual who has been designated by a patient's health care practitioner as a necessary caretaker for managing the well-being of the patient with respect to the use of medical cannabidiol pursuant to the provisions of Chapter 124E.

Primary Caregiver Application Process

(Paper-Based)

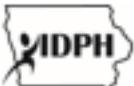
1. Submit an application to the Department.
2. Submit a written certification to the department signed by the patient's health care practitioner that the patient in the primary caregiver's care is suffering from a debilitating medical condition.
3. Attest that he/she has not been convicted of a disqualifying felony offense.
4. Submit a medical cannabidiol registration fee of \$25 to the Department.

Primary Caregiver Application (Paper-Based)

Sections:

- Primary Caregiver Information
- Patient Information
- Health Care Practitioner Certification
- Primary Caregiver Application Checklist
- *We are making the same updates to allow online registration for caregivers

\$25 application fee

	IOWA DEPARTMENT OF PUBLIC HEALTH Office of Medical Cannabidiol	For the most current information regarding this application, medical cannabis laws in the state of Iowa and more, see the official website: https://idph.iowa.gov/mcarp
MEDICAL CANNABIDIOL REGISTRATION CARD – PRIMARY CAREGIVER APPLICATION		
Mail completed application and required materials to: Iowa Department of Public Health ATTN: OMC 321 E. 12th Street Des Moines, IA 50319-0075		<input type="checkbox"/> New Caregiver <input type="checkbox"/> Renewing Caregiver <input type="checkbox"/> Have you ever applied for a Medical Cannabidiol Registration Card in Iowa? <input type="checkbox"/> Yes – same patient <input type="checkbox"/> Yes – different patient <input type="checkbox"/> No
Print clearly. Incomplete applications may be denied. Application fees are non-refundable.		
PRIMARY CAREGIVER INFORMATION		
"Primary Caregiver" means a person, who is a resident of Iowa or a bordering state, including but not limited to a parent or legal guardian, at least eighteen years of age, who has been designated by a patient's health care practitioner as a necessary caretaker taking responsibility for managing the well-being of the patient with respect to the use of medical cannabis.		
Name (Last, First, Middle Initial)		
Sex Designation <input type="checkbox"/> Male <input type="checkbox"/> Female		Date of Birth (Must be 18 or Older)
Where You Live	Permanent Iowa Address (Street, Apt. #)	
	Address (City, State ZIP Code)	
Where You Get Mail	Address (P.O. Box, Apt. #)	
	Address (City, State ZIP Code)	
Primary Phone Number		<input type="checkbox"/> Check this box if a confidential message may be left at this number.
Secondary Phone Number		<input type="checkbox"/> Check this box if a confidential message may be left at this number.
PRIMARY CAREGIVER ATTESTATION STATEMENT		
PRIMARY CAREGIVER INSTRUCTION: Complete and sign the following release statement. This statement will allow the Office of Medical Cannabidiol staff to verify information with the certifying physician(s) relating to the patient's qualifying debilitating medical condition, and the dispensing of cannabisol related to that condition. It will also allow the Office to complete the processing of your application and issuance of your Medical Cannabidiol Registration Card.		
I, _____, (primary caregiver), hereby authorize the Iowa Department of Public Health (IDPH), Office of Medical Cannabidiol, to exchange information about the patient's qualifying debilitating medical condition with his or her certifying health care practitioner, the Iowa-licensed medical cannabisol dispensaries, and the Department of Transportation in relation to the issuance of a Medical Cannabidiol Registration Card and the dispensing of any cannabisol/cannabinoid product.		
By signing below, I certify that the information on this application is complete, true and submitted for the purpose of obtaining a State of Iowa Medical Cannabidiol Registration Card. If approved for the Registration Card, I agree to the terms of the Iowa Medical Cannabidiol Act, Chapter 124.E. A copy of the act may be found at this web address: https://idph.iowa.gov/mcarp		
• To ensure confidentiality, information regarding application status will not be given over the phone. Once applications are processed, communication will be sent to your residence with further instructions for the finalization of the Registration Card.		

Health Care Practitioner Responsibilities

Is a special certificate or license needed to certify a patient's condition?

Patients and primary caregivers must obtain the certification of the patient's qualifying debilitating medical condition for the application process.

“Health care practitioner” means individuals licensed under Chapter 148 to practice medicine and surgery or osteopathic medicine and surgery in Iowa.

“Health care practitioner” shall not include a physician assistant licensed under Chapter 148C or an advanced registered nurse practitioner licensed pursuant to Chapter 152 or 152E.

HEALTH CARE PRACTITIONER CERTIFICATION

PATIENT INSTRUCTIONS: Have your physician complete this entire section. This section should be submitted as a part of your completed application to the Office of Medical Cannabidiol. Partial applications will not be accepted. The patient application must be received by the Office of Medical Cannabidiol within 60 days of the physician's signature date. Faxed and electronic copies will not be accepted.

NOTE: THIS DOES NOT CONSTITUTE A PRESCRIPTION FOR CANNABIDIOL or MEDICAL MARIJUANA.

HEALTH CARE PRACTITIONER INSTRUCTIONS: Print clearly. Answer all of the questions with information in the patient's medical record.

Patient Name

(Last, First, Middle Initial)

HEALTH CARE PRACTITIONER INFORMATION

Health Care Practitioner means an individual licensed under Chapter 148 to practice medicine and surgery or osteopathic medicine and surgery who is a patient's primary care provider. "Health Care Practitioner" shall not include a physician assistant licensed under Chapter 148C or an advanced registered nurse practitioner licensed pursuant to Chapter 152 or 152E.

Physician Name

(First, Middle Initial, Last, Suffix)

Medical License Number	License State (Must be licensed in Iowa)	License Type (Must be DO or MD)
------------------------	---	------------------------------------

Practice Address

(Street)

Practice Address

(P.O. Box, Suite #)

Address

(City, State ZIP Code)

Phone Number

Fax Number

Medical Specialty (Oncology, Neurology, Pain Management, etc.)

PATIENT'S QUALIFYING DEBILITATING MEDICAL CONDITION

INSTRUCTIONS: Please mark the debilitating medical conditions which qualify the patient for a Medical Cannabidiol Registration Card.

<input type="checkbox"/>	Cancer with severe or chronic pain
<input type="checkbox"/>	Cancer with nausea or severe vomiting
<input type="checkbox"/>	Cancer with cachexia or severe wasting
<input type="checkbox"/>	Multiple sclerosis with severe and persistent muscle spasms
<input type="checkbox"/>	Seizures, including those characteristic of epilepsy
<input type="checkbox"/>	AIDS or HIV as defined in Iowa Code, section 141A.1
<input type="checkbox"/>	Crohn's disease
<input type="checkbox"/>	Amyotrophic lateral sclerosis
<input type="checkbox"/>	Any terminal illness with a probable life expectancy of under one year and severe or chronic pain
<input type="checkbox"/>	Any terminal illness with a probable life expectancy of under one year and nausea or severe vomiting
<input type="checkbox"/>	Any terminal illness with a probable life expectancy of under one year and cachexia or severe wasting
<input type="checkbox"/>	Parkinson's disease
<input type="checkbox"/>	Untreatable Pain (<i>means any pain whose cause cannot be removed and, according to generally accepted medical practice, the full range of pain management modalities appropriate for the patient has been used without adequate result or with intolerable side effects.</i>)

Patient Name

(Last, First, Middle Initial)

HEALTH CARE PRACTITIONER CERTIFICATION

INSTRUCTIONS: Please initial all sections. All must be initialed in order for the application to be approved.

I have established a patient-provider relationship with the patient identified above.

Initials

I am a primary care provider involved in the diagnosis and treatment of this patient's debilitating medical condition.

Initials

I have determined in my medical judgment that this patient whom I have examined and treated suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol under Iowa Code, chapter 124E.

Initials

I have provided this patient with the explanatory information provided by the Iowa Department of Public Health (found on the Department's website at this web address: <https://idph.iowa.gov/Medical-Cannabidiol-Act-Registration-Card-Program/Medical-Cannabidiol-Education-Material>) on the therapeutic use of medical cannabidiol and the possible risks, benefits, and side effects of the proposed treatment.

Initials

I agree to determine, on an annual basis, if the patient continues to suffer from a debilitating medical condition and, if so, issue the patient a new certification of that diagnosis.

Initials

I agree to otherwise comply with all requirements established by the Iowa Department of Public Health pursuant to rule, and provide other information as requested.

Initials

I understand that I may provide, but have no duty to provide, this written certification of debilitating medical condition for the applicant patient.

Initials

HEALTH CARE PRACTITIONER ATTESTATION

I designate the person(s) named in the Primary Caregiver Section as Primary Caregiver(s) in relation to the patient to manage the patient's well-being with respect to the use of medical cannabidiol pursuant to the provisions of Iowa Code chapter 124.E.

I certify under penalty of perjury that the foregoing statements and all information provided by me on this application are true and correct. I understand the law provides severe penalties (fine and/or imprisonment) for the willful submission of known false information. **I understand this application does not, by itself, provide authorization for the Medical Cannabidiol Registration Card for the above named patient/and/or caregiver(s).**

Health Care Practitioner

Signature

Date of

Signature

Iowa Code 124E provides that health care practitioners are under no obligation to provide the written certification of a medically debilitating condition for a patient.

Information on possible risks, benefits, and side effects is provided by IDPH. A health care practitioner is providing that information to the patient and/or primary caregiver.

A health practitioner does NOT:

- Prescribe;
- Recommend;
- Set dosing recommendations.

A health practitioner DOES:

- Certify that he/she has relationship with the patient and is involved in the patient's care;
- Certify that patient has a qualifying debilitating condition;
- Provide educational material to the patient as provided by the department;
- Agree to recertify the patient annually to ensure that program criteria are met;
- Agree to provide information to the department.



Iowa Department of Public Health Protecting and Improving the Health of Iowans

Gerd W. Clabaugh, MPA
Director

Kim Reynolds
Governor

Adam Gregg
Lt. Governor

Information About the Therapeutic Use of Medical Cannabidiol

What Patients are Eligible to Receive a Medical Cannabidiol Registration Card?

A list of debilitating medical conditions for which patients are eligible to receive a medical cannabidiol registration card can be found here: <https://idph.iowa.gov/mcarcp/who-is-eligible>

What is a Cannabinoid?

A cannabinoid is a class of chemical compounds that occurs naturally in some plants and animals. There are more than 60 naturally occurring cannabinoids. Cannabinoids have been found useful for compassionate use treatment of some debilitating medical conditions.

What is CBD?

Cannabidiol (CBD) is the name of one type of cannabinoid found in the *Cannabis* plant family that has potential therapeutic uses. CBD is not psychoactive. It does not alter the state of mind of a person who uses it.

What is THC?

Tetrahydrocannabinol (THC) is another type of cannabinoid found in the *Cannabis* plant family that also has potential therapeutic uses. THC is the cannabinoid with psychoactive effects and is known for the mind-altering "high" it can produce.

How do CBD, THC and other Cannabinoids Work?

CBD, THC and other cannabinoids attach themselves to certain receptors in the body. The human body produces certain cannabinoids on its own, and has two receptors, called CB1 and CB2 receptors.

- CB1 receptors are found throughout the body, but many of them are in the brain. In general, the CB1 receptors in the brain deal with coordination and movement, pain, emotions and mood, thinking, appetite, and memories.
- CB2 receptors are more common in the immune system. CB2 receptors have an effect on inflammation and pain.

It appears that most cannabinoids do not act on either receptor directly. Instead, CBD and THC seem to influence the body to use more of its own cannabinoids. Products that contain both CBD and THC have the ability to stimulate and reverse both CB receptors. In some disease conditions this allows beneficial therapeutic effects while minimizing some of the less desirable psychoactive effects sometimes experienced from the use of THC.

Potential Health Benefits

Due to the way CBD, THC and other cannabinoids act in the body, they may have some potential health uses. Certain research (including cell culture, animal models, and clinical studies in patients) has shown cannabinoids to have a range of effects that may be therapeutically useful, including anti-seizure, antioxidant, neuroprotective, anti-inflammatory, analgesic, and anti-anxiety properties.

How are CBD, THC and other Cannabinoids Used?

CBD, THC and other cannabinoids are taken in a variety of ways. They may be ingested orally, rubbed on the skin as a cream or an oil, inhaled in a nebulizable form or taken as a suppository.

Potential Side Effects of CBD

Small-scale studies that have looked into the safety of the use of CBD by adults and have found that CBD use is generally well tolerated across a wide range of doses. There have been no known findings of significant central nervous system side effects (effects on vital signs or mood) among people who use CBD sparingly or more heavily. The most common side effects of CBD are:

- Fatigue/tiredness.
- Diarrhea.
- Changes in appetite or weight.
- Dry mouth.
- Low blood pressure.

Special Considerations for use of CBD:

- Parkinson's disease - Some early research suggests that taking high doses of CBD can make muscle movement and tremors worse in people with Parkinson's disease.
- Pregnancy and breast-feeding - There is not enough reliable information about the safety of taking CBD while pregnant or breastfeeding. CBD is not recommended for use by pregnant or breastfeeding women.

Potential Side Effects of THC

THC has been studied in detail and those effects are summarized here. The most common side effects of THC are:

- Unusual changes in mood or behavior, feeling depressed.
- High or low blood pressure.
- Seizures.
- Drowsiness, dizziness, lightheadedness, or a false sense of well-being (euphoria). Patients using THC should not drive or do anything that could be dangerous until they know how THC affects them. Standing up slowly from a sitting or lying position can lessen the chance of getting dizzy.
- THC can be habit-forming (in 1 out of every 10 people).
- There have been reports of altered brain development in young patients, thought impairment, short term memory impacts, and chronic psychosis disorders.
- Rarely, allergic reactions: itching or hives, swelling in the face or hands, chest tightness.

Special Considerations for the use of THC:

- Pregnancy and breast-feeding - There is not enough reliable information about the safety of taking THC while pregnant or breastfeeding. THC is not recommended for use by pregnant or breastfeeding women.

Contraindications for the use of THC:

- Disulfiram or metronidazole use within the past 14 days.
- Use of disulfiram or metronidazole within 7 days of using THC.
- Use of the following drugs:
 - Amiodarone, amitriptyline, amoxapine, amphetamine, amphotericin B, atropine, buspirone, clarithromycin, cycloserine, desipramine, erythromycin, fluconazole, itraconazole, ketoconazole, lithium, phenobarbital, ritonavir, scopolamine, warfarin.
- Use of alcohol.
- Sleep aids.
- Allergy medications.
- Narcotics.
- Grapefruit or grapefruit juice.

As with any new or alternative treatment option, a patient should discuss the potential health benefits, side effects, and risks of using CBD, THC and other cannabinoids with a qualified healthcare practitioner before using them. The dose and form will vary depending on the condition being treated.

What protections does the law provide for physicians who provide the certification?

“Section 15. 124E.11 Use of Medical Cannabidiol – Affirmative Defenses.

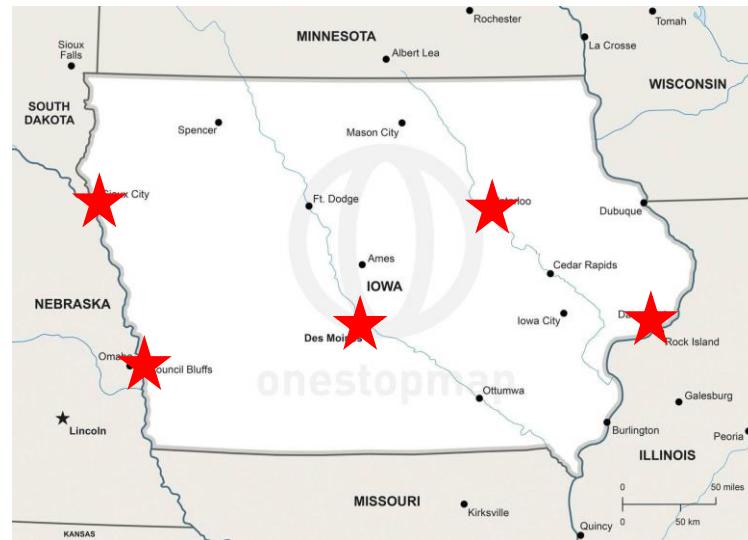
A health care practitioner, including any authorized agent or employee thereof, shall not be subject to prosecution for the unlawful certification, possession, or administration of marijuana under the laws of this state for activities arising directly out of or directly related to the certification or use of medical cannabidiol in the treatment of a patient diagnosed with a debilitating medical condition as authorized by this chapter.”

How will my patients obtain medical cannabidiol in Iowa?

By December 1, 2018, patients and primary caregivers will be able to access medical cannabidiol for their debilitating conditions through licensed dispensaries.

Five dispensaries have now been licensed:

1. Have a Heart Compassion Care, Council Bluffs
2. Have a Heart Compassion Care, Davenport
3. Iowa Cannabis Company, Inc., Waterloo
4. MedPharm Iowa, Windsor Heights
5. MedPharm Iowa, Sioux City



Legal Manufacturing and Dispensing of CBD in Iowa

Manufacturing

Iowa Code 124E calls for two in-state manufacturers to be licensed by December 1, 2017.

Manufacturing applicants pay a fee of \$7,500 upon application + a \$10,000 deposit per owner for the Iowa Department of Public Safety to conduct background record checks.

An annual fee will be assessed to the two licensed manufacturers.

A competitive bid resulted in the licensing of one manufacturer – MedPharm Iowa on December 1, 2017.

A second competitive bid in Spring 2018 resulted in the licensing of Iowa Relief on July 1, 2018. They will have products available by July 1, 2019.

Dispensing

Iowa Code 124E –
Three Provisions for
CBD Dispensing

1. Licensing of up to five in-state dispensaries:
 - Completed;
 - Ready to dispense CBD by December 1, 2018
2. Licensing of two out-of-state dispensaries:
 - Licensed by December 1, 2017;
(The department did not pursue this approach per guidance from the Attorney General's office)
3. Reciprocity with the State of Minnesota and its dispensaries:
(Minnesota law does not allow this)

Forms and Quantities

Proposed Administrative Rules

Medical Cannabidiol forms approved (154.14(2)):

1. Oral forms, including but not limited to:
 - a) Tablets
 - b) Capsules
 - c) Liquids
 - d) Tinctures
 - e) Sub-lingual forms.
2. Topical forms, including but not limited to:
 - a) Gels
 - b) Ointments, cream, or lotions.
 - c) Transdermal patches.
3. Nebulizable Inhaled forms.
4. Suppositories, including but not limited to:
 - a) Rectal
 - b) Vaginal

No forms may be edible (i.e., contained in food) or smoked.

Forms and Quantities

Proposed Administrative Rules

Proposed quantities allowed (154.14(1)):

A 90-day supply is the maximum amount of each product that shall be dispensed by a dispensary at one time.

Forms and Strengths Proposed by MedPharm Iowa

Strengths proposed by MedPharm Iowa:

Elevated THC: THC 3% and CBD 0.3%

- (delivers 10 mg THC and 1 mg CBD per 0.3 ml dose)

Balanced: THC 3% and CBD 3%

- (delivers 10 mg THC and 10 mg CBD per 0.3 ml dose)

Low THC: THC 0.3% and CBD 3%

- (delivers 1 mg THC and 10 mg CBD per 0.3 ml dose)

Elevated CBD: THC 0.1% and CBD 10%

- (delivers 1 mg THC and 100 mg CBD per 1 ml dose)

Forms and Strengths Proposed by MedPharm Iowa

Strengths proposed by MedPharm Iowa:

Comfort: 3% THC and 0.3% CBD (10:1 THC:CBD)

- (delivers 7.5 mg THC and .75 mg CBD per 0.25 ml dose)

Restore: 3% THC and 6% CBD (1:2 THC:CBD)

- (delivers 7.5 mg THC and 15 mg CBD per 0.25 ml dose)

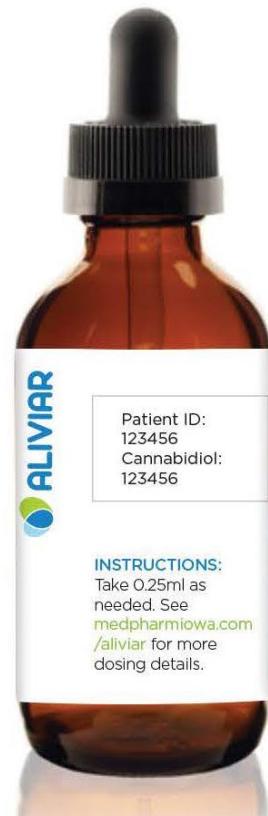
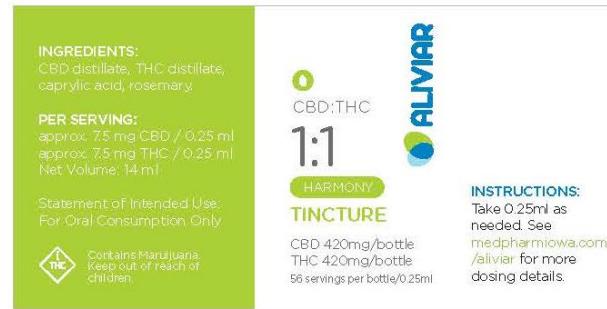
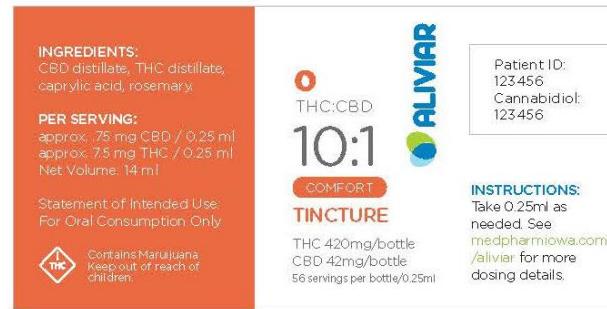
Harmony: 3% THC and 3% CBD (1:1 THC:CBD)

- (delivers 7.5 mg THC and 7.5 mg CBD per 0.25 ml dose)

Calm: 0.3% THC and 6% CBD (1:20 THC:CBD)

- (delivers 0.75 mg THC and 15 mg CBD per 0.25 ml dose)

Aliviar – Tincture products



MedPharm Iowa Products

CONTAINER/ FRONT LABEL



SAFETY / COMPONENTS



Reversible Cap
Rule 154.21(1) a.
Child-resistant & Elderly
Patients – Easy Open



Tamper-evident seal
located under the cap



Barcode for traceability,
located on bottom of
bottle.

CONTAINER / FRONT LABEL



SAFETY / COMPONENTS



Tamper-evident seal
wrapped around the
closure



Child Safety – Pinch &
Turn closure



Turn and click for
accurate dose delivery



Barcode for traceability,
located on bottom of
bottle.

Forms and Strengths Proposed by MedPharm Iowa

Forms Proposed – Years 2-3

Rapidly dissolvable oral strips (sublingual) – strengths to be determined

Bio-adhesive strips – across the skin (transdermal) – strengths to be determined

Nebulizable – strengths to be determined

Other Forms Considered:

Bath salts – strengths to be determined (this is not a form approved by the Board of Medicine)

Prices Proposed by MedPharm Iowa - MSRP

Proposed Prices – 30-day supply:

Tincture - \$70.00

Soft gels - \$90.00

Transdermal Cream

- \$40.00 (small – 30 gm); \$60.00 (large – 60 gm)

Other Department Duties

- Develop and maintain a seed-to-sale tracking and inventory IT system and patient registration system:
 - BioMauris was awarded the contract;
 - On-pace for completion and licensee training
- Oversee laboratory testing administrative rules and processes to ensure products are safe;
- Identify the contaminants for which testing will be required and the action levels at which remediation or destruction will be required;
 - This is in progress;
- Inspect manufacturers and dispensaries – ongoing.

Effectiveness Data

National Academies of Sciences, Engineering, and Medicine. 2017. *The health effects of cannabis and cannabinoids: The current state of evidence and recommendations for research*. Washington, DC: The National Academies Press. doi:10.17226/24625.

Minnesota Department of Health, *A Review of Medical Cannabis Studies relating to Chemical Compositions and Dosages for Qualifying Medical Conditions*, July 2016.

Sativex – 1:1 THC:CBD oromucosal spray – MS; Approved in 30 countries; undergoing FDA approval process in USA; GW Pharmaceuticals

Epidiolex – Oral solution of CBD – Seizure disorders – Approved by FDA in June 2018; GW Pharmaceuticals

Marinol (dronabinol)/ Nabilone - THC – FDA approved currently for nausea and loss of appetite from HIV or chemotherapy

Resources

Iowa Code 124E – The Medical Cannabidiol Act

641 Iowa Administrative Code Chapter 154 – Patient and Primary Caregiver Registration Cards, Manufacturing, Dispensing, and Medical Cannabidiol Board

Iowa Department of Public Health, Office of Medical Cannabidiol

Questions?

Office of Medical Cannabidiol (OMC)
<https://idph.iowa.gov/mcarcp>
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QUESTIONS



THANKS FOR ATTENDING!

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**JOIN US TUESDAY, SEPT. 11:
PBM CONTRACTS**

Questions? Contact David Schaaf at dschaaf@iarx.org or 515-270-0713