

Iowa Code Chapter 124E

Iowa Medical Cannabidiol Act



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



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Disclosures

I have no conflict of interest or financial interest with this presentation.



What We Will Cover

- Introduction to Iowa Code Chapter 124E
 - The Medical Cannabidiol Board
 - Registration card application process
 - Who is a patient? Who is a primary caregiver?
 - Qualifying conditions
 - Healthcare Practitioner responsibilities, protections and education
 - Manufacturing, Dispensing and Inspections
 - Available forms, product composition, product testing and cost
- 

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.

* The Iowa Department of Public Health was charged by the legislature to write the administrative rules for the program

HF 524 was enacted on 5/12/2017



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 (**vacant**);
- 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.

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
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 Chapter 124E 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 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/cbd/patient-registration>

Office of Medical Cannabis > Patient Registration

For Patients And Caregivers

Patient Registration

Caregiver Registration

Petition To Add Qualifying Conditions

For Physicians

For Law Enforcement And Public Safety

For Manufacturers And Dispensaries

Medical Cannabis Advisory Board

Laws And Regulations

Program Data And Statistics

Adult Patient Registration

The following information is designed to help patients understand the process of becoming a registered patient in Iowa's medical cannabis program. Minor patients (under 18 years old) will require a primary caregiver, and need the caregiver to complete the caregiver registration, which is similar to the patient registration.

What You Will Need to Apply

- 1. Healthcare certification form completed and signed by your doctor**
 - [Healthcare Practitioner Certification Form](#)
 - Certifies you have a qualified debilitating medical condition
- 2. Photo ID**
 - A valid Iowa driver's license
 - A valid Iowa non-operator's identification card
- 3. Proof of reduced fee (if in one of the eligible programs below)**
 - Social Security Disability Benefit Recipient (copy of current benefit notice)
 - Supplemental Security Income Payment Recipient (copy of current receipt)
 - Iowa Medicaid (copy of current member card)
 - Hawk-I (copy of member card)
- 4. Payment of \$100 for annual card (\$25 if eligible for reduced fee)**
 - We accept debit card, credit card and e-check payments when applying online
 - We accept cash or paper checks when applying in person or through the mail

Online Registration Coming Soon...

Register Using Paper Form Here

- Register by mail or in person by downloading paper form here
- [Adult Patient Registration Form](#)

Who is a 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).

* Minor patients will not be given a patient registry number, but will be tied to their designated primary caregiver

Patient Application Process

- We would prefer patients use our new online patient application form, but will continue to provide our paper-based process for those with access issues

1. 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.
2. Submit a patient application form to the Department
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)

Online Patient Application (Now Live)

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

1.

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Patient Application

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

New or Renewal Application? *

First Name Middle Name Last Name

Patient's First Name * Patient's Middle Name Patient's Last Name *

Pick your gender designation

Date of Birth

Birth Date (MM/DD/YYYY)*

Drivers License or State ID

License or State ID # *

Primary Phone Number

Primary Phone *

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

2.

I qualify for the reduced fee.

Options Please sign: mCBD patient attestation 5

Start

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

POWERED BY Adobe Sign

I have read and completed the above attestation.

SUBMIT

You must click the submit button to complete your application!!

Patient Application (Paper-Based)

Sections:

- Patient Information
- Primary Care Giver Designation – Optional
- Health Care Practitioner Section
- Health Care Practitioner Certification
- Patient Application Checklist
- \$100/\$25 application fee



IOWA DEPARTMENT OF PUBLIC HEALTH
Office of Medical Cannabis

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/cbd>

MEDICAL CANNABIDIOL REGISTRATION CARD – ADULT PATIENT APPLICATION

For adult patients with a designated primary caregiver, please also have the caregiver complete the primary caregiver application. For patients under 18 years old (minors), please use the primary caregiver application and not this adult patient application.

We now accept electronic applications!			
For online submission of registration applications, go to https://idph.iowa.gov/cbd			
For paper applications, mail completed application and required materials to: Iowa Department of Public Health ATTN: OMC 321 E. 12 th Street Des Moines, IA 50319-0075			
Print clearly. Incomplete applications may be denied. Application fees are non-returnable.			
PATIENT INFORMATION			
<input type="checkbox"/> New Patient <input type="checkbox"/> Renewing Patient			
Name (First, Middle, Last)			
Sex Designation <input type="checkbox"/> Male <input type="checkbox"/> Female		Date of Birth (Must be 18 or Older)	County where you live
Where You Live	Permanent Iowa Address (As it appears on state ID) (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.	
E-mail Address			
PATIENT ATTESTATION STATEMENT			
PATIENT INSTRUCTION: Complete and sign the following release statement. This statement will allow the Office of Medical Cannabis staff to verify information with the certifying physician(s) relating to your qualifying debilitating medical condition, and the dispensing of cannabis related to that condition. It will also allow the Office to complete the processing of your application and issuance of your Medical Cannabis Registration Card.			
I, _____, (patient), hereby authorize the Iowa Department of Public Health (IDPH), Office of Medical Cannabis, to exchange information about my qualifying debilitating medical condition with my certifying health care practitioner, the Iowa-licensed medical cannabis dispensaries, and the Department of Transportation in relation to the issuance of a Medical Cannabis Registration Card, and the dispensing of any cannabis/cannabinoid product.			

Qualifying Debilitating Medical Conditions

- Ulcerative colitis has passed approval of our medical advisory board, as well as the board of medicine
- PTSD, ADHD and Autism are being deliberated at our upcoming advisory board meeting

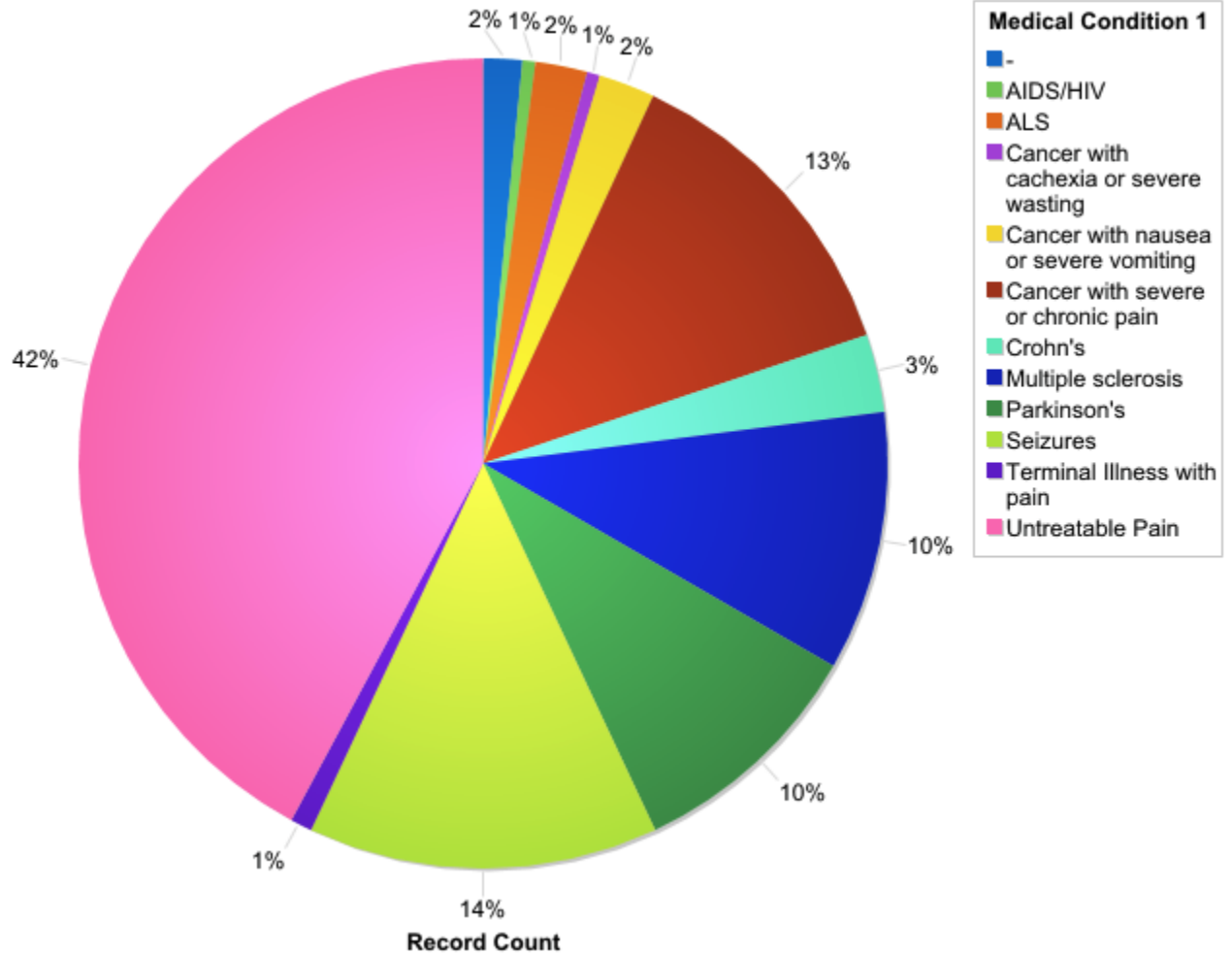
1. **Cancer**, if the underlying condition or treatment produces one or more of the following:
 - Severe or chronic pain.
 - Nausea or severe vomiting.
 - Cachexia or severe wasting.
2. **Multiple Sclerosis** with severe and persistent muscle spasms.
3. **Seizures**, including those characteristic of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

Qualifying Debilitating Medical Conditions

* Ulcerative colitis has passed approval of our medical advisory board, and the board of medicine has agreed to add this condition to their administrative rules

7. **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.
8. **Parkinson's Disease.**
9. **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.*

Patient Percentages By Medical Condition



Who is a Primary Caregiver?

Means a person who:

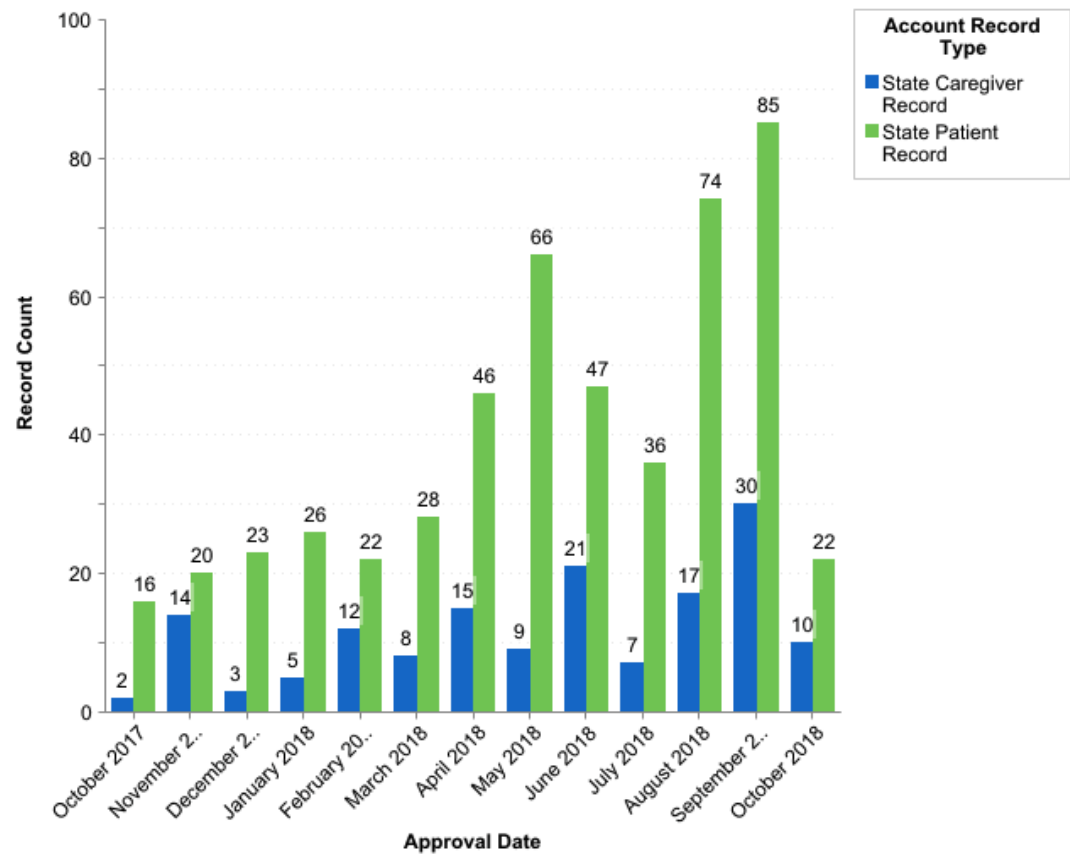
- Is a resident of this state or a bordering state (Illinois, Minnesota, Missouri, Nebraska, South Dakota, or Wisconsin);
- Is at least 18 years of age; and
- Is a patient's parent or legal guardian, or another individual who has been designated by a patient's health care practitioner as a necessary 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

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.

Patient and Physician Attrition

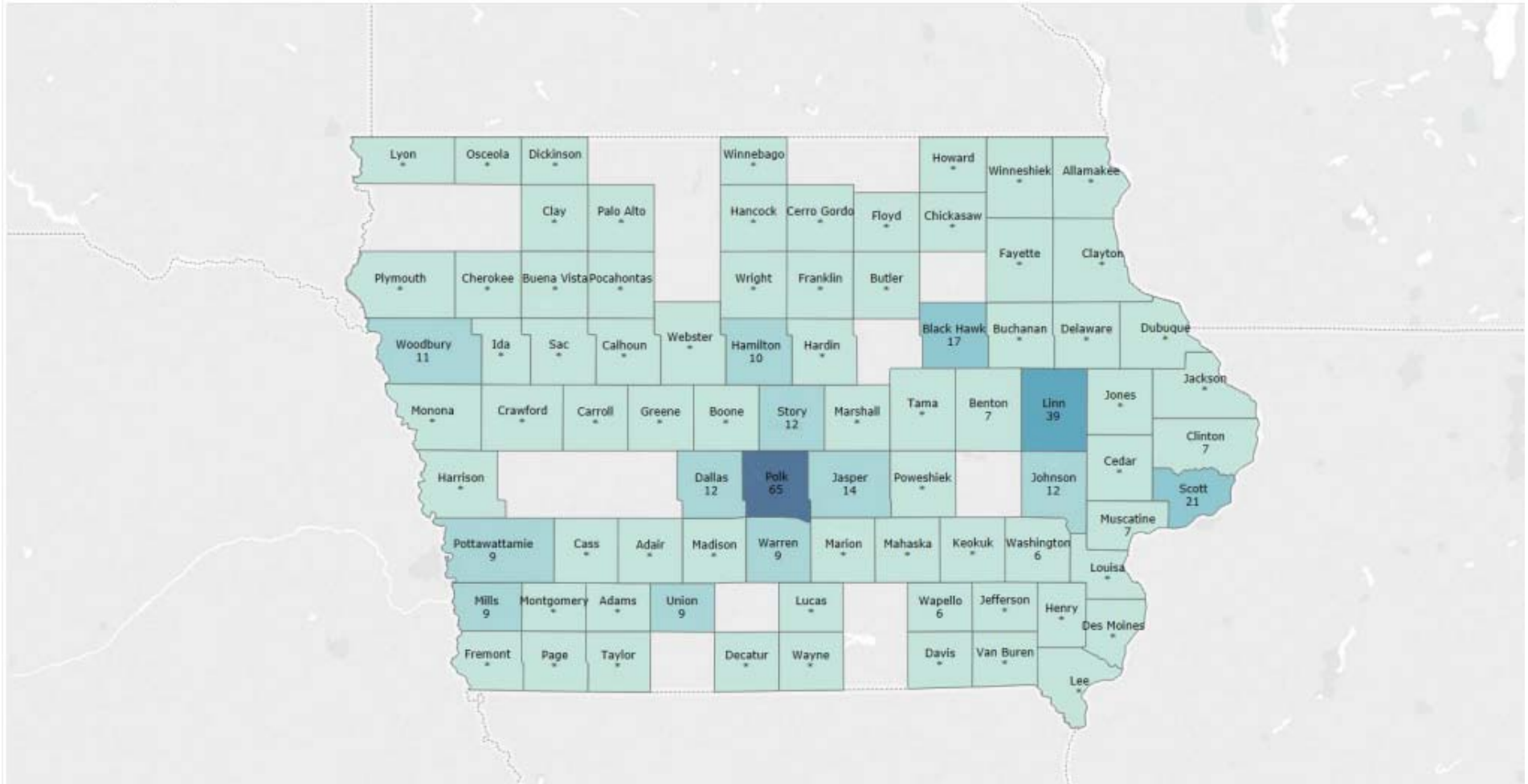
Role in Registry	Number of People
Issued Cards: Number of patients and caregivers with active, DOT-issued registration cards.	438
Healthcare Practitioners: Unique number of physicians who have certified patients.	269



Cards Issued By County

DOT Issued

Patient counts by county, issued by DOT and not expired
Values of 5 or fewer are indicated by *
One record not displayed because of incorrect Zip code



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.

What cannabidiol- specific CME opportunities are available for physicians in-general?

There are multiple groups across the country who offer courses accredited for CME credits, some of these options are listed below:

<https://idph.iowa.gov/cbd/For-Physicians>

Online Continuing Medical Education (CME) Opportunities

Cannabinoids for Chronic Pain - Dr. Jolene Smith DO, DABA, DABA-PM and Dr. Karry Smith PhD, MPH. The link below will take you to a webinar of a CME hosted by Des Moines University College of Osteopathic Medicine on September 6, 2018. The cost for this online activity is \$15 and is approximately 50 mins. You must log-in or create an account before enrolling in this education activity.

- CME Objectives:
 - List the FDA-approved cannabinoid-based medications
 - Determine when cannabinoids might be considered for a patient with chronic pain
 - Weigh the risks and benefits of cannabinoid therapy
 - Identify Iowa guidelines and regulations pertaining to the use of cannabinoid therapy
- Continuing education credit:
 - **MD** - This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Iowa Medical Society (IMS). Des Moines University (DMU) is accredited by the IMS to provide continuing medical education for physicians. DMU designates this enduring materials activity for 1.0 AMA PRA category 1 credit(s). Physicians should claim only the credit commensurate with the extent of their participation.
 - **DO** - Des Moines University (DMU) is accredited by the American Osteopathic Association (AOA) to provide osteopathic continuing and speciality credits commensurate with the extent of the physician's participation in this activity.
- Take the following link to register for this course: <https://cme.dmu.edu/content/cannabinoids-chronic-pain>

TheAnswerPage is offering 22.5 CME, ANCC and ACPE credits in medical marijuana and risk management at a reduced subscription fee.

- [TheAnswerPage](#)

The Medical Cannabis Institute is the nation's leading online provider of ACCME and ANCC-certified medical education for the clinical application of medical cannabis. Our science-based courses help healthcare professionals deliver quality care and address patient questions. Use the customized link below to view our curricula and course offerings to earn CME credits at a reduced price.

- [The Medical Cannabis Institute](#)

Cannabis Expertise offers live on-site medical cannabis program and live webinar sessions - offering participants the opportunity to ask questions of the faculty.

- [Cannabis Expertise](#)

What educational resources does the department provide for physicians?

The department is charged with implementing and regulating the medical cannabidiol program. However, we do provide resources on our website for physicians looking to further understand medical cannabidiol and it's therapeutic utility.


<https://idph.iowa.gov/cbd/For-Physicians>

Educational Resources for Physicians

The following document was created by the Minnesota Department of Health. It is a summary of clinical trials and prospective observational studies in humans, published in peer-reviewed journals and focuses on medical cannabidiol formulations consistent with Iowa's medical cannabidiol program. Physicians looking for guidance on dose for a given qualifying condition may find it helpful.

- [A Review of Medical Cannabis Studies relating to Chemical Compositions and Dosages for Qualifying Medical Conditions](#) 

The following document was created by Health Canada as an educational document for healthcare practitioners. It contains information on the endocannabinoid system, clinical pharmacology, dosing, potential therapeutic uses (by condition), precautions, warnings, adverse side effects and overdose/toxicity information.

- [Information for Healthcare Practitioners: Cannabis and the Cannabinoids](#) 

The following document is a report of patient and physician experiences during the first year of Minnesota's medical cannabis program. It was done between July 1, 2015, and June 30, 2016, with 1,660 enrolled patients and 577 physicians. While Iowa and Minnesota's programs are not identical, this survey and summary document may give patients and physicians an idea of what to expect.

- [Minnesota Year-One Report: A Survey of Patients and Physicians](#) 

Treatment for pain or untreatable pain is the the most certified condition for medical cannabidiol in Iowa. Minnesota has also done research and surveys with their patient population on this specific condition. For more information on patient outcomes and experiences with this condition, please see the following document:

- [Intractable Pain Patients in the Minnesota Medical Cannabis Program](#) 

For physicians looking for even more research and in-depth articles, the Minnesota Department of Health has created a repository of reports and articles on their list of qualifying conditions and medical cannabis in-general. The link below will bring you to this repository.

- [Minnesota Department of Health: Review Articles and Reports](#)

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 CANNIBIDIOL 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.)

Healthcare Practitioner Attestation and Opt-In Option

HEALTH CARE PRACTITIONER ATTESTATION - REQUIRED	
<p>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.</p> <p>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 certification does not, by itself, provide authorization for the Medical Cannabidiol Registration Card for the above named patient/and/or caregiver(s).</p>	
Health Care Practitioner Signature	Date of Signature
<p>(OPTIONAL) Opt in Statement: <i>I hereby authorize the Iowa Department of Public Health to release my name and practice address to patients seeking certification of a qualifying debilitating medical condition for purposes of obtaining a medical cannabidiol registration card. I understand that by checking the opt in box below, my name and practice address will be provided to patients upon request. I further acknowledge that I must notify the Iowa Department of Public Health, Office of Medical Cannabidiol in the event I choose to withdraw this authorization at a future time.</i></p> <p>Opt in selection <input type="checkbox"/> (check this box and sign below if you are opting in)</p>	
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 a 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.
- 

Patient Information Sheet



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/cbd/For-Patients-and-Caregivers>

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 to be 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 used as a suppository.

<https://idph.iowa.gov/Medical-Cannabidiol-Act-Registration-Card-Program/Medical-Cannabidiol-Education-Material>

Potential Side Effects of Cannabinoids

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 include:

- 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.

THC has been studied in detail and those effects are summarized here.

The most common side effects of THC include:

- 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, such as itching or hives, swelling in the face or hands, or 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.
 - THC can cause drowsiness and impaired cognition - *If a patient has ingested or taken medical cannabidiol products containing THC, they should refrain from operating heavy machinery or a motor vehicle.*

Contraindications and Drug-Interactions When Using Cannabinoids

- **Drug Interactions**
 - Interaction with clobazam (specifically the active metabolite, desmethylclobazam, to increase concentrations and side effects)
 - Interaction with several other antiepileptic drugs that can result in increased side effects, such as drowsiness, fatigue, and lack of concentration.
 - Interaction with valproate to increase the risk of liver toxicity
 - Liver toxicity that can result in increased liver enzymes and possible serious liver damage.
- **Contraindications**
 - Disulfiram or metronidazole use within the past 14 days.
 - Use of disulfiram or metronidazole within 7 days of using THC.

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

124E.12 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.”

<https://idph.iowa.gov/cbd/For-Physicians>

For Patients And Caregivers
Patient Registration
Caregiver Registration
Petition To Add Qualifying Conditions
For Physicians
For Law Enforcement And Public Safety
For Manufacturers And Dispensaries
Medical Cannabidiol Advisory Board
Laws And Regulations
Program Data And Statistics

Medical Cannabidiol Information for Physicians

The following information is designed and organized for physicians. As defined in Iowa Code chapter 148C, a physician means a person who is currently licensed in Iowa to practice medicine and surgery or osteopathic medicine and surgery. It does not include a physician assistant licensed under Iowa Code chapter 148C or an advanced registered nurse practitioner.

Physician Roles and Responsibilities

Prior to a patient's submission of an application for a medical cannabidiol registration card pursuant to this rule, a health care practitioner shall do all of the following:

1. Determine, in the health care practitioner's medical judgment, whether the patient whom the health care practitioner has examined and treated suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol as defined by this chapter, and if so determined, provide the patient with a written certification of that diagnosis by completing the health care practitioner section of the application form provided for this purpose on the department's website.
2. Provide explanatory information to the patient as provided on the department's website about the therapeutic use of medical cannabidiol and the possible risks, benefits, and side effects of the proposed treatment. This information is found in Patient Information Sheet
3. Subsequently, the health care practitioner shall do the following:
 - i. 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.
 - ii. Otherwise comply with all requirements in this chapter and requests from the department for more information. A health care practitioner may provide, but has no duty to provide, a written certification pursuant to this rule.

Affirmative Defenses for Health Care Practitioners

Iowa Code chapter 124E.12 (1) - 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.

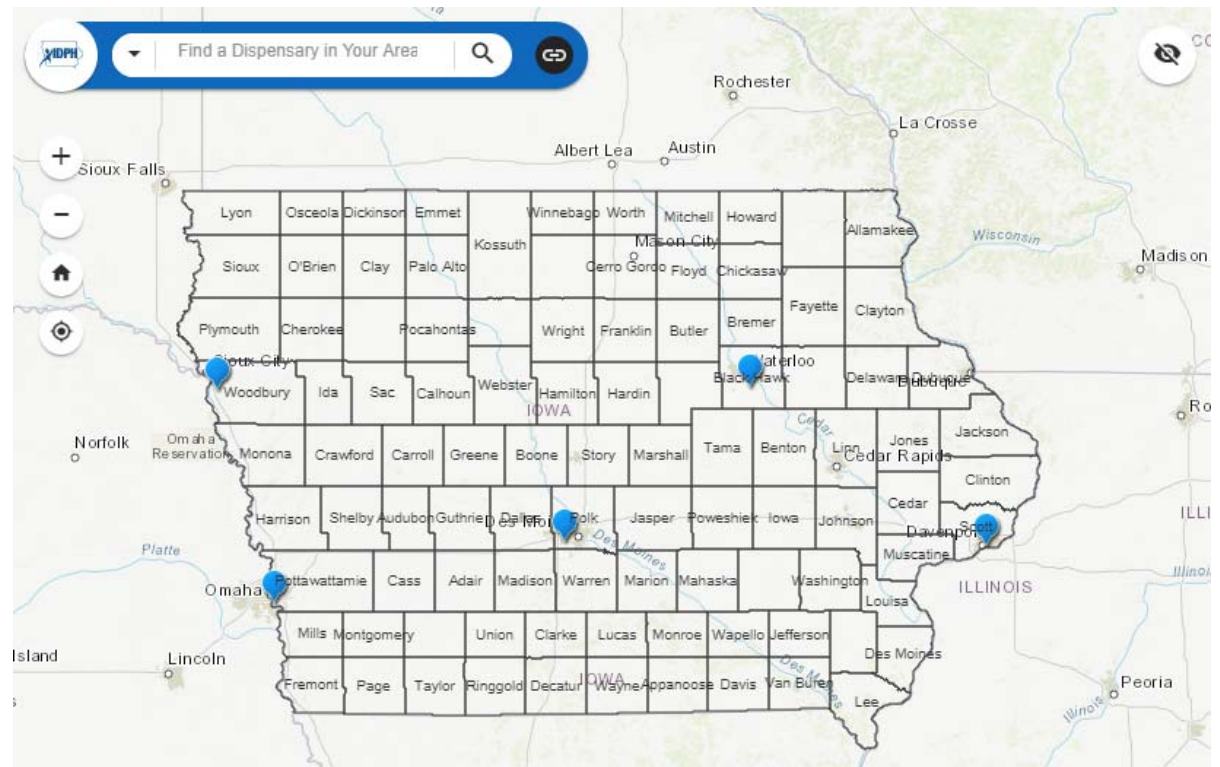
Iowa Code chapter 124E.12 (6) - Any health care practitioner, including any authorized agent or employee thereof, are not subject to any civil or disciplinary penalties by the board of medicine or any business, occupational, or professional licensing board or entity, solely for activities conducted relating to a patient's possession or use of medical cannabidiol as authorized under this chapter. Nothing in this section affects a professional licensing board from taking action in response to violations of any other section of law.

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 and a \$10,000 deposit per owner for the Iowa Department of Public Safety to conduct background record checks.
- An annual fee of \$150,000 will be assessed to each of 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
- Dispensary License fees are \$75k/year

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, per guidance from the Attorney General's office*
3. Reciprocity with the State of Minnesota and its dispensaries:
 - *Minnesota law does not allow this*

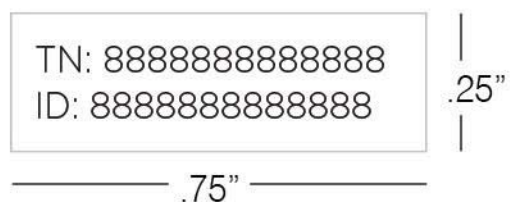


Inspections

- Iowa Code 124E charges IDPH with doing inspections for licensee compliance.
- We have used methodologies from other states, and are inspecting for compliance with all administrative rules and mandated processes.
- Using “operational readiness” model and inspecting as systems come on-line.
- MedPharm has completed compliance inspections for all security and cultivation infrastructure, will be inspecting extraction systems in the coming weeks.
- Dispensary inspections are tentatively scheduled for mid to late October.

How does the State monitor licensee compliance?

- The Department has built a seed-to-sale tracking software that tracks the end-to-end processes of cannabidiol manufacturing and dispensing
 - Built by an experienced vendor from the pharmaceutical IT space
- Tracks movement of all plants, processing, employees, transport, testing information, patient purchasing data, inventory and much more
- Salesforce backbone provides the State with sophisticated tracking and reporting capabilities



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.

Over-The-Counter CBD Products

IDPH Position Statement on OTC-CBD Products



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

Gerd W. Clabaugh, MPA
Director

Kim Reynolds
Governor

Adam Gregg
Lt. Governor

August 17, 2018

IDPH Position Statement on CBD Product Availability in Iowa

The Department of Public Health (Department) has received a number of inquiries about the legality of CBD products currently sold in the state of Iowa. It is the position of the Department that CBD products are not legal in the state of Iowa, with the following four exceptions:

1. The following appropriately prescribed, FDA-approved drugs: Marinol, Syndros, Cesamet
2. Epidiolex, produced by GW Pharmaceuticals, which has been approved by the FDA but is awaiting action by the Drug Enforcement Administration of the Department of Justice
3. Sativex, produced by GW Pharmaceuticals, as part of a FDA-approved clinical trial
4. Products produced and approved pursuant to [Iowa Code chapter 124E](#), the Medical Cannabidiol Act, that contain less than 3% tetrahydrocannabinol (THC) and are in a form recommended by the Medical Cannabidiol Board, approved by the Board of Medicine, and adopted by the Department pursuant to administrative rule (see [641—154.14\(124E\)](#) for the approved forms).

Products manufactured in the state under the provisions of Iowa Code chapter 124E will be available at Department-licensed dispensaries only, starting in late 2018.

The Department's authority under Iowa Code chapter 124E does not extend to regulation of the sale or use of the types of CBD products that may be currently available at retailers throughout the state. Consumers of these products should be aware that these products have not been approved for use under either a federal or state of Iowa regulatory program. Agencies with enforcement authority in this area include the federal Drug Enforcement Administration, the federal Food and Drug Administration, county attorneys and law enforcement agencies.

For additional information, please contact: Sarah Reisetter, IDPH Deputy Director, sarah.reisetter@idph.iowa.gov, 515-201-0926.

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**.

* The state's seed to sale tracking software will track every patient that enters, as well as all purchasing data for all dispensaries. If suspicious behavior is detected, the department has the ability to notify law enforcement.

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 and 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)

MedPharm Iowa Products

Composition of Products

<p>CBD:THC 20:1</p> <p>CALM</p> <p>Forward CBD Seizures Crohn's Parkinson's Untreatable Pain</p>	<p>CBD:THC 2:1</p> <p>SOOTHE</p> <p>Elevated CBD Parkinson's Untreatable Pain</p>	<p>CBD:THC 1:1</p> <p>HARMONY</p> <p>Balanced formula. Cancer Untreatable Pain AIDS/HIV ALS MS</p>	<p>CBD:THC 1:20</p> <p>COMFORT</p> <p>Forward THC Cancer Untreatable Pain AIDS/HIV Terminal Illness</p>
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Tincture



20:1 **CALM** TINCTURE

CBD 1500 mg THC 75 mg SIZE 14 ml

Each 0.25mL dose of our CALM tincture contains over 25mg of CBD and less than 2mg of THC.



1:1 **HARMONY** TINCTURE

CBD 300 mg THC 300 mg SIZE 14 ml

Each 0.25mL dose contains around 5mg of THC and 5mg of CBD.



1:20 **COMFORT** TINCTURE

CBD 14 mg THC 280 mg SIZE 14 ml

Each 0.25mL dose contains 5mg of THC and 0.25mg of CBD.

MedPharm Iowa Products

Capsules



20:1 CALM CAPSULE

CBD 600 mg THC 30 mg
SIZE 30 capsules

Each capsule contains 20mg of CBD and 1mg of THC.



1:20 COMFORT CAPSULE

CBD 1.5 mg THC 30 mg SIZE 6 capsules

Our Comfort trial capsules allow patients to find the right formulation. Each capsule contains 5mg of THC and 0.25mg of CBD.



1:1 HARMONY CAPSULE

CBD 150 mg THC 150 mg
SIZE 30 capsules

Each capsule contains 5mg of THC and 5mg of CBD.

Lotion



2:1 SOOTHE CREAM

CBD 420 mg THC 210 mg SIZE 56 grams

This formula has no scent additive. Each 1/2 tsp portion of our unscented cream contains 17.5mg of CBD and 8.75mg of THC.

Product Testing and Safety

Iowa's State Hygienic Laboratory will be conducting all product testing, which will be done at the **process** and final **product** lot stages.

Testing will be done for the following:

- *Metals, Pesticides, Microbiological Impurities, Solvents and Cannabinoid Content*

Table 3 - Contaminant Analysis & Acceptance Criteria			
Analyte	Action Level	Comment	Guideline
Metals		Metals testing is required for every process lot	FDA Q3D, elemental impurities guidance
Arsenic	1.5 ppm		
Cadmium	0.3 ppm		
Lead	1.0 ppm		
Mercury	0.5 ppm		
Analyte	Action Level	Comment	Guideline
Microbiological Impurities		Total yeast and mold testing is done for process lots and microbial testing is done for product lots	American Herbal Pharmacopeia (USP 1111), State of Iowa Hygienic Laboratory
	-		
Analyte	Action Level	Comment	Guideline
Pesticides		Pesticide Testing is required for every process lot	APHL "Guidance for State Medical Cannabis Testing Programs" (2016)
	-		
Analyte	Action Level	Comment	Guideline
Solvents		Solvent testing is required for every process lot	Based on disclosed use by manufacturer
Ethanol	5000 ppm		

Prices
Proposed by
MedPharm
Iowa - MSRP

Proposed Prices – 30-day supply:

 TINCTURES	\$50 - \$130
 CAPSULES	\$30 - \$130
 TRIAL CAPSULES	\$10 - \$25
 CREAMS	\$65 - \$85

* Iowa patients must pay for products out-of-pocket. Currently, there is no form of reimbursement of insurance. This is universal in this industry in America.

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?

Thank You,

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Protecting and Improving the Health of Iowans

